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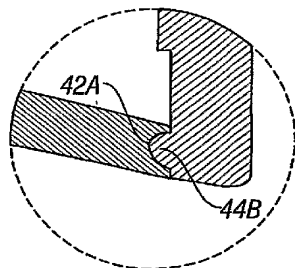
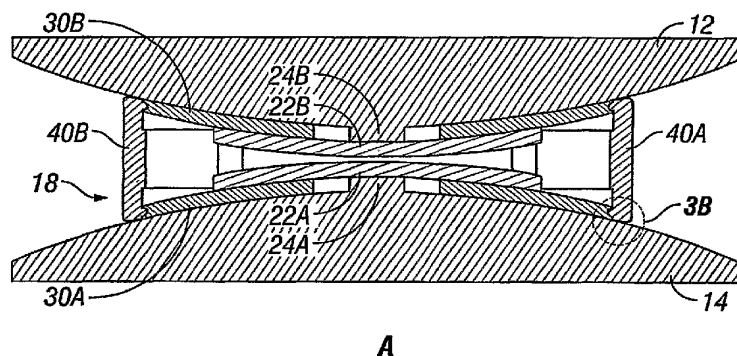
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(54) Title: ARTIFICIAL SPINAL DISK



(57) Abstract: An artificial spinal disk comprises a central capsule that is configured to slide laterally within the disk space with one or more of flexion, extension, and lateral bending of the spine so as to shift an instantaneous center of rotation of the artificial disk. In one embodiment, the invention comprises an artificial spinal disk comprising a first plate having an inwardly directed surface, a second plate having an inwardly directed surface facing generally toward the inwardly directed surface of the first plate, and a central capsule with outwardly directed opposed faces that slidably mate with the inwardly directed surfaces of the first and second plates.

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ARTIFICIAL SPINAL DISK

Background of the Invention

A wide variety of artificial spinal disk designs have been developed over the past several
5 years. Some designs, such as those described in U.S. Patent Nos. 6,001,130 and 5,123,926 include
resilient plastic or fluid filled bag type structures that are placed between adjacent vertebra. These
designs provide flexibility, but present the risk of rupture or breakage, and can be difficult to contain
effectively within the disk space. Other designs have attempted to use ball-and socket type couplers
between endplates or other retaining devices attached to the vertebral bodies. Currently, devices
10 which use metal-metal interfaces rather than resilient bodies are favored for their reliability and
strength. However, these types of couplings do a poor job of imitating the natural relative movement
of vertebral bodies separated by a natural anatomical disk. Furthermore, this type of replacement
disk typically focuses all the forces from weight and motion in a single direction and on a very small
part of each vertebral body. This can cause excessive stress on the bone in the area where the
15 artificial disk connects to the vertebral body. Improved designs that reduce these problems are
needed in the art.

Summary of the Invention

An artificial spinal disk comprises a central capsule that is configured to slide laterally
within the disk space with one or more of flexion, extension, and lateral bending of the spine so as to
20 shift an instantaneous center of rotation of the artificial disk. In one embodiment, the invention
comprises an artificial spinal disk comprising a first plate having an inwardly directed surface, a
second plate having an inwardly directed surface facing generally toward the inwardly directed
surface of the first plate, and a central capsule with outwardly directed opposed faces that slidably
mate with the inwardly directed surfaces of the first and second plates.

25 In another embodiment, an artificial spinal disk comprises a plurality of separate pieces,
wherein the separate pieces are configured and sized to be placed in the disk space separate from one
another. The pieces comprise couplers such that the separate pieces are attached to form a
completed artificial disk only after installation within the disk space. In one such embodiment, the
separate pieces of the artificial disk comprise at least first and second bone plates and a central
30 capsule.

Methods of spine surgery are also provided. In one embodiment, a method of spine surgery
comprises placing a first portion of an artificial disk into a disk space; and
separately placing one or more additional portions of the artificial disk into the disk space and
mechanically coupling the additional portions to one or more portions previously placed inside the

disk space so as to assemble a complete artificial disk within the disk space from artificial disk pieces that are separate outside of the disk space.

In another embodiment of the invention, a surgical kit for spinal surgery comprises a first bone plate configured for attachment to a first vertebral body;

5 a second bone plate configured for attachment to a second vertebral body; and

a central capsule configured to couple to the first bone plate and the second bone plate;

wherein the first bone plate, the second bone plate, and the central capsule are uncoupled from one another to allow for separate installation in a disk space during spine surgery. In some embodiments, the first bone plate and the second bone plate comprise a plurality of uncoupled

10 segments.

Brief Description of the Drawings

FIG. 1A-1C is a side view of a first embodiment of an artificial spinal disk with a sliding capsule.

15 FIG. 2A-2C is a side view of a second embodiment of an artificial spinal disk with a sliding capsule.

FIG. 3 is a cross sectional view of a specific embodiment of the sliding capsule design of FIG. 1.

FIG. 4 is an exploded view of the disk of FIG. 3.

20 FIG. 5 is a cross sectional view of a specific embodiment of the sliding capsule design of FIG. 2.

FIG. 6 is a perspective view of a multi-piece bone plate for coupling the sliding capsules to upper and lower vertebral bodies.

FIG.s 7A and 7B are top and side views of a specific embodiment of a bottom bone plate.

FIG.s 8A and 8B are top and side views of a specific embodiment of a top bone plate.

25 FIG. 9 is a side view of the capsule of FIG. 3 (in cross section) coupled to the top and bottom bone plates of FIG.s 7 and 8.

FIG. 10 illustrates an alternative artificial disk embodiment.

FIG. 11 illustrates a three-piece bone plate coupling the sliding capsules to upper and lower vertebral bodies.

30 FIG. 12 is a side cutaway view of the artificial disk embodiment of FIG. 10.

Detailed Description

One embodiment of an artificial disk in accordance with the invention is shown in Figures 1A, 1B and 1C. In this embodiment, endplates 12, 14 sandwich a sliding central capsule 18. As shown in these Figures, a first plate 12 defines a first inwardly directed surface 13 and the second plate 14 defines a second inwardly directed surface 15. A central capsule 18 defines opposed outwardly directed surfaces 17, 19 that slidably mate with the inwardly directed surfaces of the

plates. Thus, the central capsule can slide toward and away from opposed edge portions of the endplates as the relative endplate orientation changes during flexion, extension or lateral bending of the motion segment in which the artificial disk is installed. With this design, the endplates 12, 14 can also rotate with respect to one another as the central capsule slides between them. In this embodiment, the endplates have convex spherical contours, and the central capsule 18 is generally cylindrical with top and bottom surfaces that are concave spherical contours mating with the convex spherical contours on the endplates. Thus, the central capsule 18 is generally cylindrical with a hour-glass shaped cross-section.

Another embodiment of an artificial disk with a central sliding capsule is illustrated in Figures 2A, 2B, and 2C. In this embodiment, the inner surfaces 13, 15 of the endplates 12, 14 are concave rather than convex. The capsule 18 includes mating convex surfaces 17, 19 that slides along the endplate surfaces in a manner analogous to that shown in Figures 1A, 1B, and 1C.

There are a variety of important benefits of such a sliding capsule 18. One is that the instantaneous center of rotation of the motion segment is allowed to move around inside the disk space with the capsule during lateral bending, flexion, and extension. Also, the central capsule spreads mechanical stresses over a larger portion of the endplates and thus over the adjacent vertebral bodies as well. This mimics the natural behavior of a spinal disk much better than existing artificial disk designs. Also, this leads to a reduced tendency for migration and loosening following installation, since stresses due to spinal movements are not continually focused in the same direction or location.

One mechanical design for implementing the above described sliding capsule is shown in Figures 3 and 4. Referring now to these figures, retainer disks 22A and 22B are secured to respective end plates 14 and 12 on pedestals 24A and 24B with screws (designated 26A, B, C, and D in Figure 4). The retainer disks also have a spherical contour substantially matching that of the endplates. The pedestals 24A, 24B may be captured in the end plates in recesses or they may be integral with the end plates as shown in Figure 3. Each retainer disk is secured tightly to the pedestal with the screws such that it does not move with respect to the endplate. Because of the pedestal, however, the underside of each retainer disk is raised up off of the inside spherically contoured surface of the endplate by the height of the pedestal. In an alternative embodiment, a single screws can be used, or a single screw can be made integral with their respective retainer disks 22A, 22B, with the retainer disks held away from the surfaces of the plates without the pedestals by screwing the threaded shafts down to a stop in the plate, for example. If desired, a ring clip or other device could be used to fix unthreaded shafts for the retainer disks 22A, 22B, such that the disks themselves are fixed away from the surfaces of the plates but are allowed to rotate about their central axes.

Captured underneath each endplate, between the surface of the endplate and the underside of each retainer disk, are sliding inner disks 30A and 30B, which are also spherically contoured to match the contour of the endplate inner surfaces. The thickness of these sliding disks 30A, 30B is selected with respect to the height of the pedestals 24A, 24B such that each disk 30A and 30B are slidably captured between the inner surface of the endplate and the underside of the respective retainer disk. The two separate endplates, with attached sliding and retainer disks, are held in facing relation by a sliding inner disk clamp, which in this embodiment comprises two parts, designated 40A and 40B in these Figures, and which are held to each other with screws. The clamp pieces 40A and 40B engage the edges of the sliding disks 30A and 30B in a tongue and groove arrangement. In the pictured embodiment, the edge of each sliding inner disk 30A and 30B is provided with a groove 42A and 42B, and the inner surface of the clamp is provided with a pair of extending flanges 44A and 44B. When the flanges on the clamp engage the grooves of the sliding disks 30A and 30B, a cylindrical sliding assembly with an hourglass shaped cross section is created comprising the clamp 40A, 40B and the sliding disks 30A, 30B. This sliding assembly couples the endplates via the position of the sliding disks under the retainer disks and is slidable with respect thereto between the endplates and the retainer disks 22A and 22B.

The amount of lateral motion and rotation that the sliding assembly is allowed is governed by the shape and size of central openings in the sliding disks with respect to the shape and size of the pedestals 24A and 24B fixed to the center of the endplates. The sliding disks will be able to slide away from the center and rotate until the edges of the openings in the sliding disks contact the sides of the pedestals. In one embodiment, it has been found advantageous for the relative dimensions of these features to allow for a few millimeters of lateral movement. For round pedestals and openings, rotation around the central axis of the device is unlimited throughout 360 degrees. It has been found advantageous, however, to use the oblong shapes shown in Figure 4, which limit rotation to about 30-60 degrees.

An alternative embodiment is illustrated in cross section in Figure 5. This embodiment corresponds to the capsule design illustrated in general in Figure 2. In this design, the retainer disks 22A and 22B and the inner sliding disks 30A and 30B are curved in the opposite contour from the embodiment of Figures 1 and 3-4. Thus, in the embodiment of Figure 5, the concave sides of the retainer disks and sliding disks face each other, and the convex sides face corresponding concave surfaces of the endplates 12, 14. Operation of this embodiment is analogous to that described above, with the inner sliding disks 30A and 30B sliding along the endplate inner surfaces and between the retainer disks and the endplate surfaces during flexion, extension, and lateral bending of the spinal column.

One advantage of the design of Figure 5 is that the clamp 40A, 40B of Figures 3 and 4 can be eliminated. This can be accomplished by including mating press-fit flanges 46A, 46B around the

outer edges of the two sliding disks 30A, 30B. To assemble the device, each half is constructed comprising an endplate, a retainer disk, and a sliding inner disk. Then, the two halves are coupled with a snap fit that engages the flanges 46A, 46B and holds the two halves together.

5 All components of the device may be made of biocompatible metals and metal alloys such as stainless steel or titanium. In one embodiment, the sliding coefficient of friction between the disks and the endplate surfaces is reduced by coating the sliding surfaces with a low friction coating. One example of such a useful coating is known as Casidiam™ diamond-like carbon coating. This coating typically includes carbon, hydrogen, and possibly some additional dopant materials and is a mixture of tertagonal diamond type carbon crystal structure and trigonal graphitic carbon crystal
10 structure. It is a commercially available coating and is used in a variety of industrial and medical applications requiring hardness, chemical inertness, biocomaptibility, and low friction.

The device may be installed in a variety of ways. The device may, for example, be installed in an anterior surgical procedure using installation and securement methods currently used for artificial disks of conventional design. For example, the endplates 12, 14 could include vertically
15 extending central fins to engage the vertebral bodies on either side of the disk. This installation technique, however, has serious drawbacks. First, anterior installation is inherently risky due to the presence of the large blood vessels that run down the anterior of the spinal column. These vessels are especially vulnerable in the event the artificial disk needs to be removed, as revision surgeries must contend with scar tissue and adhesions that form in the surgical field and attach to these
20 vessels. It is therefore desirable to provide an artificial disk design that is installed via a posterior or posterior-lateral approach. Although beneficial from a surgical point of view, the spinal cord, facets, lamina, and other bony structures in the posterior of the spine limit the available insertion space. This difficulty has limited the availability of posterior inserted artificial disks. To resolve this difficulty, and to increase the use of minimally invasive procedures, an especially advantageous
25 embodiment has been designed in which the artificial disk is placed inside the disk space in several separate individual smaller pieces and is assembled within the disk space.

In one such embodiment, a pair of bone plates, each of which comes in two pieces, are installed and fixed to the upper and lower vertebral bodies. The bone plates include aligned channels into which a cassette comprising the central capsule 18 plus the two endplates 12, 14 is
30 inserted. The artificial disk thus comes in a five-piece assembly that is inserted into the disk space one piece at a time, allowing for a smaller incision and surgical field and making posterior installation of an artificial disk a practical surgical alternative.

Bone plates which may be used in one such embodiment are illustrated in Figures 6 through 8. Figure 6 is a general conceptual 3-D view from above an upper bone plate. Figures 7A-B and
35 8A-B show plan views and side views of upper and lower bone plates according to one embodiment of the invention.

In this embodiment, each bone plate includes a larger section 54 and a smaller section 52. The two sections are coupled together by a tongue and groove mating region 58. In the embodiment of Figure 6, the larger section 54 includes a dovetail groove on a straight interior edge, and the smaller section includes a mating dovetail flange on an adjacent straight interior edge. The two pieces 52, 54 are further held together with a screw 60 (Figures 7 and 8) that is installed into a countersunk hole in the smaller section 52 and which terminates in a threaded hole in the larger section 54. When installed, this screw holds the two parts 52, 54 firmly together such that relative motion along the grooved mating region 58 is prevented after the pieces are installed.

The bone plates may also incorporate captured pins 72 that are deployed into the vertebral body after installation. A variety of pin deployment methods are known and could be used, including those described in U.S. Patent Nos. 5,800,547; 5,123,926; and 5,102,950.

When mated as shown in Figures 7A and 8A, the two sections 52 and 54 create a dovetail channel 70 that extends diagonally on the surface of each bone plate. As described briefly above, the channels 70 accept mating dovetail flanges which extend from the outer surfaces of the endplates 12, 14 of Figures 1 to 3. In this way, the cassette comprising the end-plates and sliding capsule can itself be slid into position between the bone plates after installation of the bone plates.

In one embodiment, disk installation proceeds as follows. A lateral posterior hemilaminotomy incision is made and the natural disk is resected in a conventional manner. For the bone plate design shown in Figures 6-8, this incision would be on the left of the spine. After removal of the natural disk, the larger of the two bone plate sections 52 for either the top or bottom vertebral body is inserted through the incision. This section of the bone plate is then pushed laterally over to the right side of the disk space into alignment with the right side of the vertebral body and such that the groove on its flat interior edge runs substantially straight from back to front. The captured pins 72 are now deployed. The most convenient method is typically the insertion of an expandable device that presses the pins into place in the facing bone tissue. After the larger section 54 is installed, the smaller section 52 is installed by sliding it straight into the left side of the disk space such that its dovetail flange is engaged with the dovetail groove in the first section 54 and such that the channel 70 is aligned across the entire bone plate. The pins of the second installed section 52 are then deployed in the same manner as the first. This same procedure is repeated to attach a bone plate to the other vertebral body. To ensure that the channels 70 in both bone plates are appropriately aligned along their length and with each other, it is possible to use a tool that can slide into both channels to test that they do not diverge in position or direction from back left to front right along the bone plate surfaces.

After the bone plates of Figures 7 and 8 are installed, the cassette comprising the endplates 12, 14, and central sliding capsule 18 is inserted by mating a dovetail flange on the outer surfaces of the endplates 12/14 (not shown in Figures 3 and 4) to the dovetail grooves 70 and sliding the cassette

into position between the bone plates and approximately the center of the disk space. The cassette can be held in place with a set screw 80. A conceptual side view of an assembly is pictured in Figure 9.

5 An embodiment having a central capsule similar to that described above with reference to Figures 2 and 5 is illustrated in Figures 10-12. As with the embodiment of Figure 5, sliding disks 30A, 30B slide between the endplate inner surfaces and the bottom surfaces of inner retaining disks 22A, 22B. The retaining disks, in this embodiment, comprise threaded shafts that are screwed into threaded through holes 82A, 82B in the end plates 12, 14. After they are threaded down to the appropriate clearance, the bottom of the shafts are orbited in place to lock them tightly and prevent
10 any rotation or movement out of position. In this embodiment, the endplates 12, 14 are captured in between the bone plates through central orifices 92, 94. Grooved posts 96A, 96B extend from each endplate 14, 12 respectively. Captured in each grooved post is a snap ring. When the posts are engaged in the bone plates, ears on each snap ring engage an internal groove 102 in the orifice of each bone plate.

15 As shown in Figure 11, the endplates may come in three parts instead of two as shown in Figures 6-8. The rightmost portion 104 may be installed first, followed by the central portion 106, and then the left-most portion 108. The portions are engaged by a series of mating dovetail tongue and groove segments. In the embodiment of Figure 11, the central portion 106 has groove segments on the left, and tongue segments on the right. With this design, a tongue and groove mating along
20 about half of the length of the bone plates can be made during installation with a sliding motion of only the length of a single dovetail segment. If desired, lips above and/or below the segments can be provided to discourage bone growth between the segments after installation.

Figure 12 illustrates the embodiment of Figure 10 after complete assembly. With this embodiment, the centerline of the device moves in accordance with the human body in relationship
25 to the centerline, mimicking the response of a natural disk.

To install the device in the spinal column, the bone plates are installed as shown in Figure 11. The bone plates may include deployable spikes or pins as described above, or they may have integral pre-deployed pins on their outer surfaces that are pressed into the vertebral bodies during installation.

30 The vertebra are then distracted to allow the central cassette comprising endplates 12, 14, central sliding capsule to be inserted between them. The vertebra are distracted to allow clearance for the posts 96A, 96B before they are set in the orifices 92, 94 in the bone plates. Once the posts are aligned with the orifices, the distraction is removed, and the posts drop into the orifices, engaging each snap ring 98A, 98B in its respective groove in the bone plate. The snap rings may be
35 dimensioned to deform slightly during installation and snap into place, or a tool can be used to compress the rings slightly and allow the posts to engage the orifices. Toll access holes 106, 108

can be provided for this purpose, and to compress the rings for cassette removal, should removal be necessary.

5 The facets can also be addressed at the same time the artificial disk is being placed, and attention to the spinous process abutment can also be addressed at the time of surgery. In some surgical procedures, the posterior elements will also have an implant applied to the facets to improve on range of motion in flexion and extension without pain. These facet implants or articulations will facilitate the gliding mechanism that is well documented on scinradiography when the spine is taken through a range of motion in flexion, extension, lateral bend and torque. If the facet joint is not addressed, which is a significant stabilization unit of the motion segment, there may continue to be problems with back pain. At the time of our artificial disk implantation, the capsule of the facet joint 10 may be removed, and a metal on metal artificial facet may be inserted to minimize pain and to preserve movement.

The facet arthroplasty will be an articulation with the inferolateral facet and superomedial facet. This arthroplasty will have a mechanism that will allow flexion, extension and lateral translation to occur. This arthroplasty may be accomplished by opening the facet joint and placing 15 the implants on the articular cartilage (as illustrated in Figure 2 for example). In may cases there may hypertrophy or arthrosis to these complexes, which may require a partial resection with a high speed burr or osteotome. Once the opening in the facet joint is achieved the arthroplasty can then be undertaken, and the implants are then attached to the inferior aspect of the ventral surface of the vertebra above and to the dorsal articulating surface of the vertebra below. With this facet 20 arthroplasty done bilaterally, which can be achieved through minimally invasive technology, and the artificial disk in place, we have now addressed the three articulations, anterior, middle column and posterior.

The spinous processes can be partially resected to give space if there is abutment noted. A space may be created between the spinous processes to allow a placement of a shield with a metal on 25 metal articulation at the spinal laminar junction of the vertebra above and below. This metal on metal articulation will give some partial support and also prevent the abutment of spinous processes which would restrict range of motion and could result in pain. This will not only give a partial ligamentous stability, but will also keep the spinous processes from abutting. As you can see, our artificial disk complex comprises both a posterior placement or lateral placement of the disk with 30 supplementing the facet and possibly the spinous processes. Therefore, the entire complex anterior, middle and posterior column can be addressed to preserve circumferential stability to the motion segment. The artificial disk embodiments described herein do not preclude the device from being placed anteriorly, but it may often be preferable to perform one incision that can address both the posterior elements, as well as the interbody disk level with that one incision. 35

This modular design has a variety of advantages. One advantage already mentioned is that the design makes a posterior surgical approach practical. The bone plates for the vertebral bodies are inserted in multiple pieces. As shown in Figure 9, the cassette itself can be made smaller than the bone plates, allowing insertion through the same small posterior lateral hemilaminotomy incision following the two-piece bone plates.

Another advantage to this design is that it allows the artificial disk to be easily replaced with a fusion cage if this becomes necessary. In such a revision surgery, the artificial disk cassette can be pulled out, and replaced with another cassette comprising a fusion cage filled with harvested bone. In some embodiments, the cassette could include an attachment point for a slap-hammer so that the cassette could be removed more easily. This process is much simpler and less traumatic than current artificial disk removal procedures. With conventional anterior installations, implant removal to perform a fusion often involves significant bone removal from the vertebral bodies to get the implant out.

The modular design described above can even be useful as a replacement for a removed disk as well. Because the bone plates are separate from the central cassette, the bone plates can be made in varying thicknesses, or two or more can be stacked, so that if bone removal from the vertebral bodies has significantly extended the height of the disk space, this can be compensated for by extended bone plate thickness. Thus, during revision surgeries, the bone plates can be exchanged for different versions having alternative thicknesses and sizes.

To further produce an easy and successful transition from artificial disk to fusion, the bone plates can be made fenestrated. In some embodiments it might be desirable to replace solid plates with fenestrated ones during the revision surgery to convert from an artificial disk to a fusion. As another alternative, fenestrated bone plates could be removably attached to solid covers that are left in place when used with an artificial disk installation but which are removed during a revision to a fusion.

WHAT IS CLAIMED IS:

1. An artificial spinal disk comprising:
 - a first plate having an inwardly directed surface;
 - a second plate having an inwardly directed surface facing generally toward said inwardly directed surface of said first plate; and
 - a central capsule with outwardly directed opposed faces that slidably mate with said inwardly directed surfaces of said first and second plates.
2. The artificial spinal disk of Claim 1, wherein at least one of said inwardly directed surfaces is convexly curved toward said central capsule.
3. The artificial spinal disk of Claim 1, wherein at least one of said outwardly directed surfaces of said central capsule is convexly curved toward a mating inwardly directed surface of a plate.
4. The artificial spinal disk of Claim 1, wherein said central capsule comprises a pair of coupled sliding disks forming said outwardly directed opposed faces.
5. The artificial disk of Claim 4, wherein said sliding disks are attached to respective first and second plates with retainer disks that slidably clamp said sliding disks between said retainer disks and said inwardly directed surfaces of said first and second plates.
6. An artificial spinal disk comprising a central capsule configured to slide laterally within the disk space with one or more of flexion, extension, and lateral bending of the spine so as to shift an instantaneous center of rotation of the artificial disk.
7. An artificial spinal disk comprising:
 - a first plate defining a first curved surface;
 - a first retainer disk affixed to said pedestal having a contour substantially matched to said first curved surface and held in spaced relation to said first curved surface;
 - a second plate defining a second curved surface;
 - a second retainer disk affixed to said second pedestal having a contour substantially matched to said second curved surface and held in spaced relation to said second curved surface;
 - a first sliding disk captured between said first retainer disk and said first curved surface;
 - a second sliding disk captured between said second retainer disk and said second curved surface, wherein said second sliding disk is coupled to said first sliding disk.
8. The artificial disk of Claim 7, wherein said first and second sliding disks are coupled along their respective edges.

9. The artificial disk of Claim 8, wherein said first and second sliding disks are coupled along their respective edges by a clamp.

10. An artificial spinal disk comprising a plurality of separate pieces, wherein said separate pieces are configured and sized to be placed in the disk space separate from one another, and wherein said pieces comprise couplers such that said separate pieces are attached to form a completed artificial disk only after installation within the disk space.

11. The artificial disk of Claim 10, wherein said separate pieces of said artificial disk comprise at least first and second bone plates and a central capsule.

12. The artificial disk of Claim 11, wherein said central capsule and said bone plates define a tongue and groove coupler.

13. The artificial disk of Claim 11, wherein at least one bone plate comprises two or more coupled segments.

14. The artificial disk of Claim 13, wherein said two or more coupled segments define at least one tongue and groove coupler.

15. A method of spine surgery comprising:

placing a first portion of an artificial disk into a disk space; and

separately placing one or more additional portions of said artificial disk into said disk space and mechanically coupling said additional portions to one or more portions previously placed inside said disk space so as to assemble a complete artificial disk within said disk space from artificial disk pieces that are separate outside of said disk space.

16. The method of Claim 15, wherein said placing a first portion comprised attaching at least a portion of a plate to a vertebral body.

17. The method of Claim 16, wherein said placing one or more additional portions comprises attaching an additional portion of said plate to said vertebral body.

18. The method of Claim 16, wherein said placing one or more additional portions comprises attaching a central capsule to said plate.

19. A surgical kit for spinal surgery comprising:

a first bone plate configured for attachment to a first vertebral body;

a second bone plate configured for attachment to a second vertebral body; and

a central capsule configured to couple to said first bone plate and said second bone plate;

wherein said first bone plate, said second bone plate, and said central capsule are uncoupled from one another to allow for separate installation in a disk space during spine surgery.

20. The surgical kit of Claim 19, wherein said first bone plate and said second bone plate comprise a plurality of uncoupled segments.

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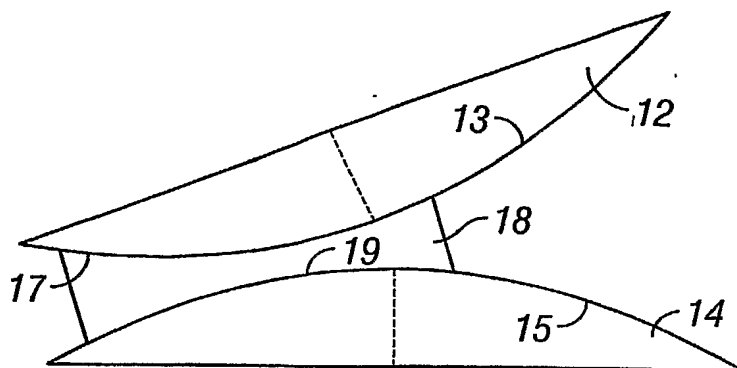


FIG. 1A

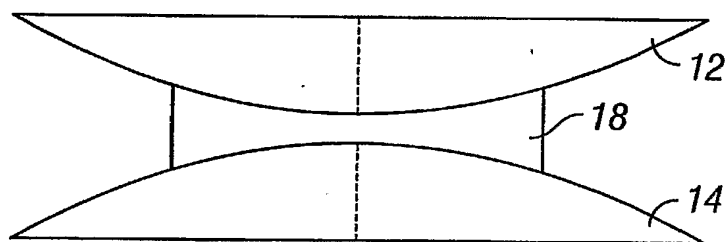


FIG. 1B

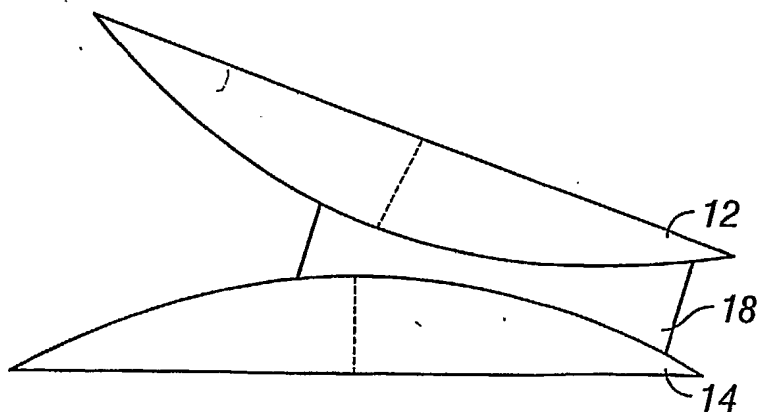


FIG. 1C

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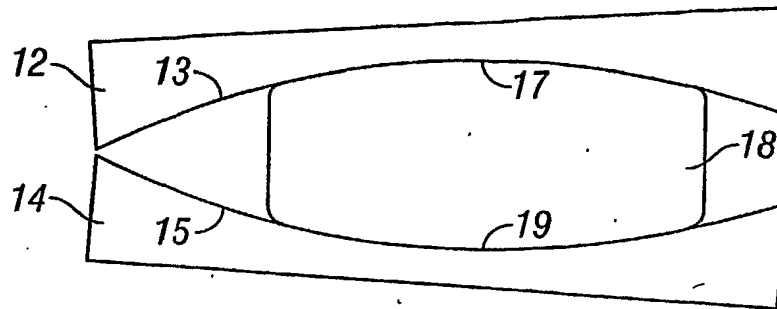


FIG. 2A

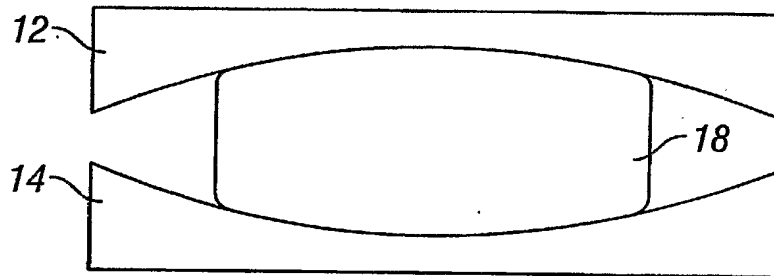


FIG. 2B

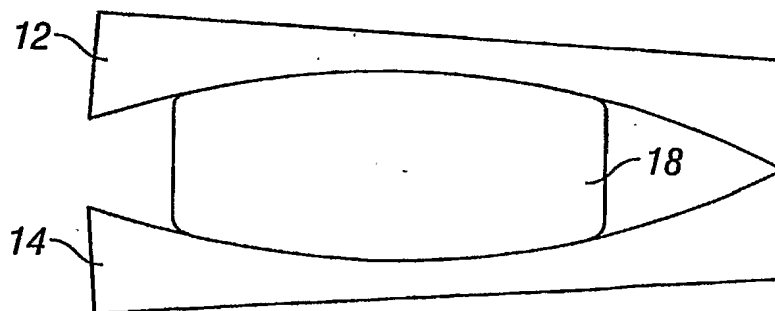


FIG. 2C

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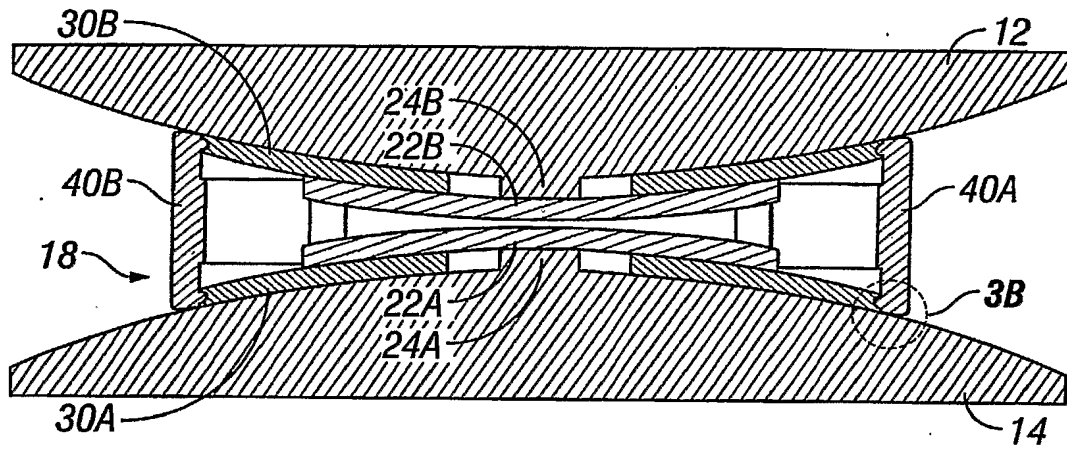


FIG. 3A

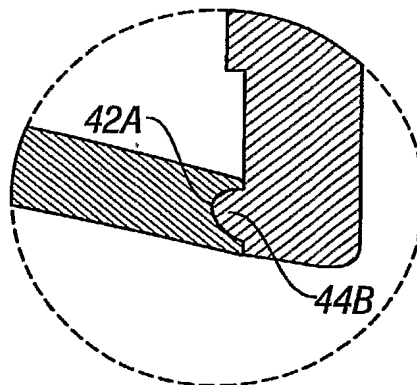


FIG. 3B

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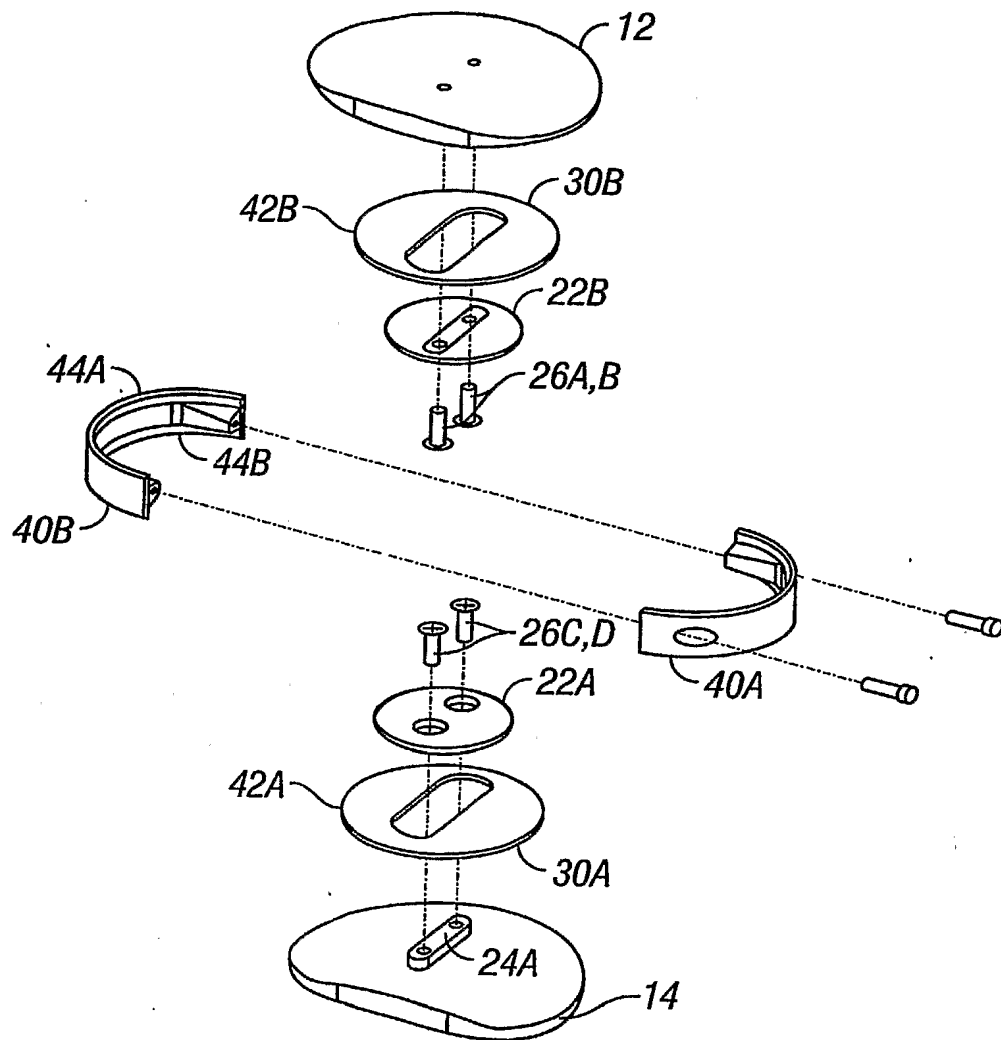


FIG. 4

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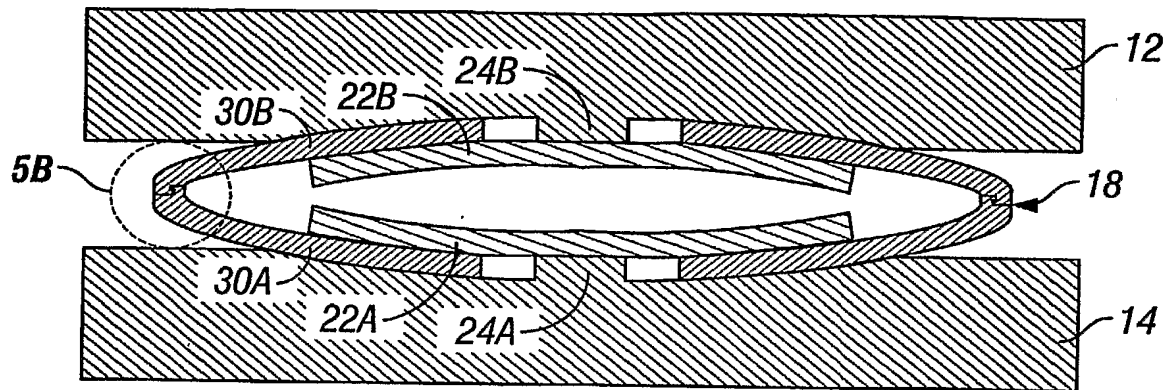


FIG. 5A

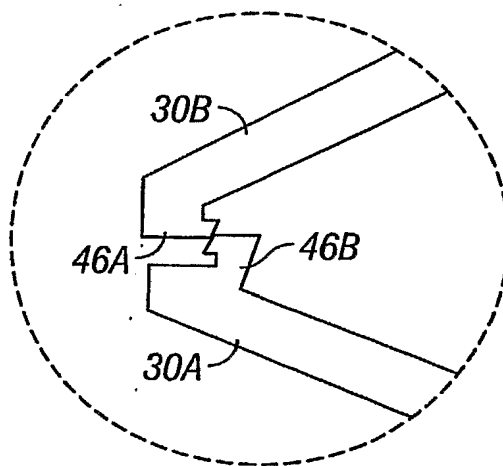


FIG. 5B

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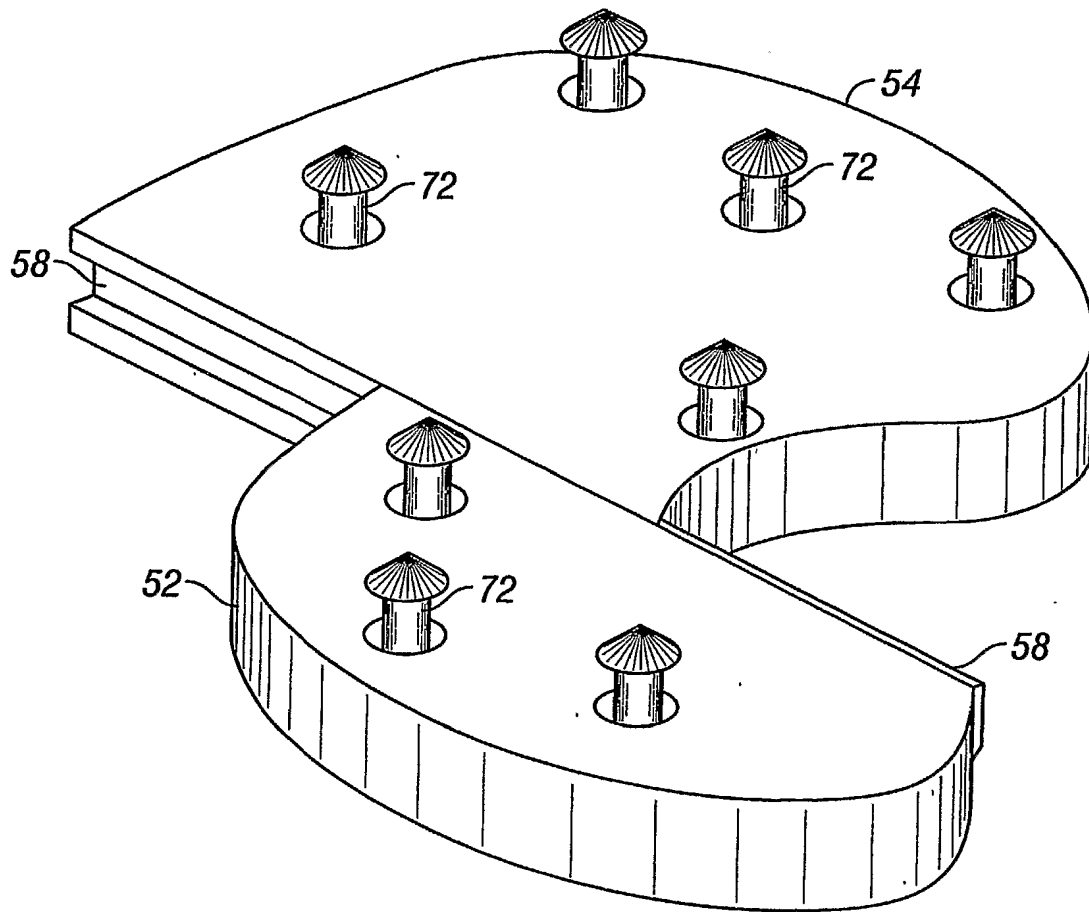


FIG. 6

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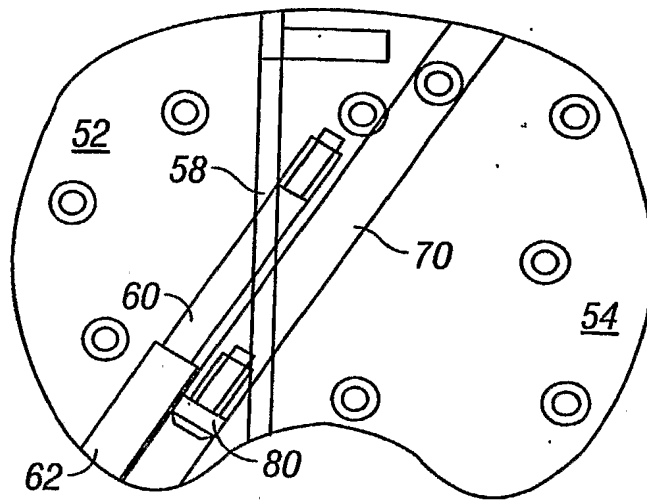


FIG. 7A

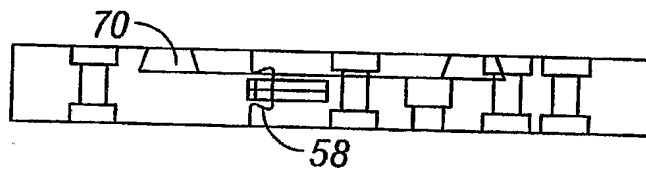


FIG. 7B

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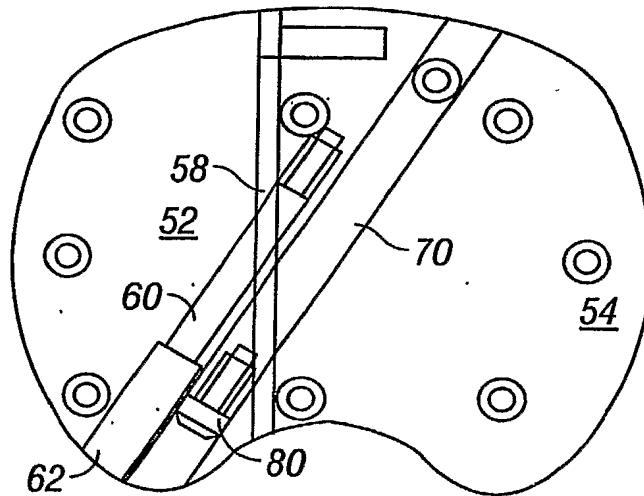


FIG. 8A

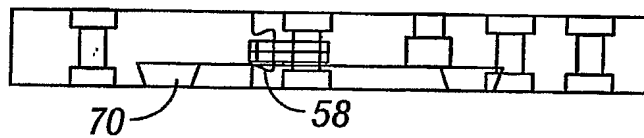


FIG. 8B

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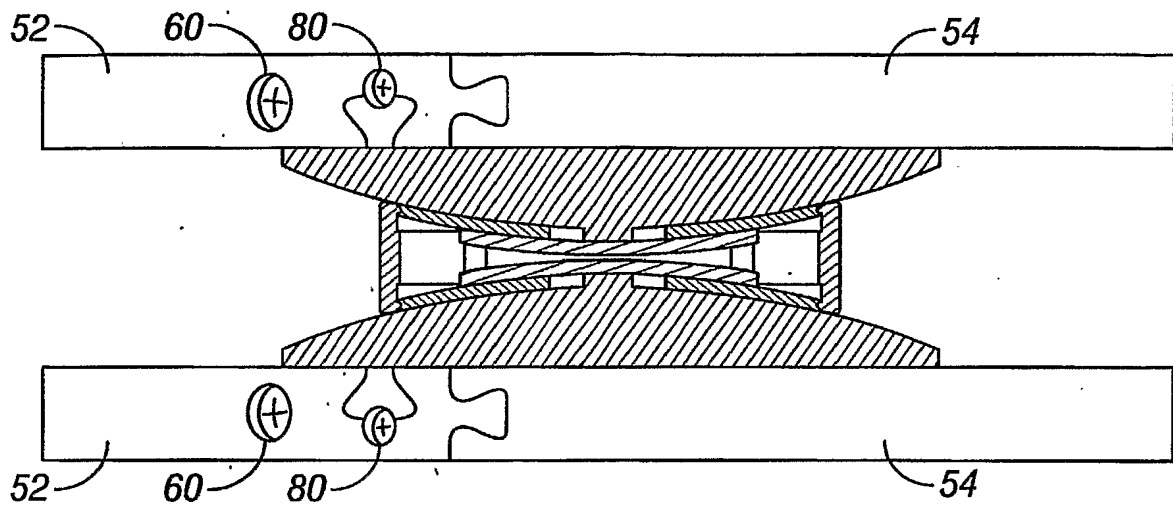


FIG. 9

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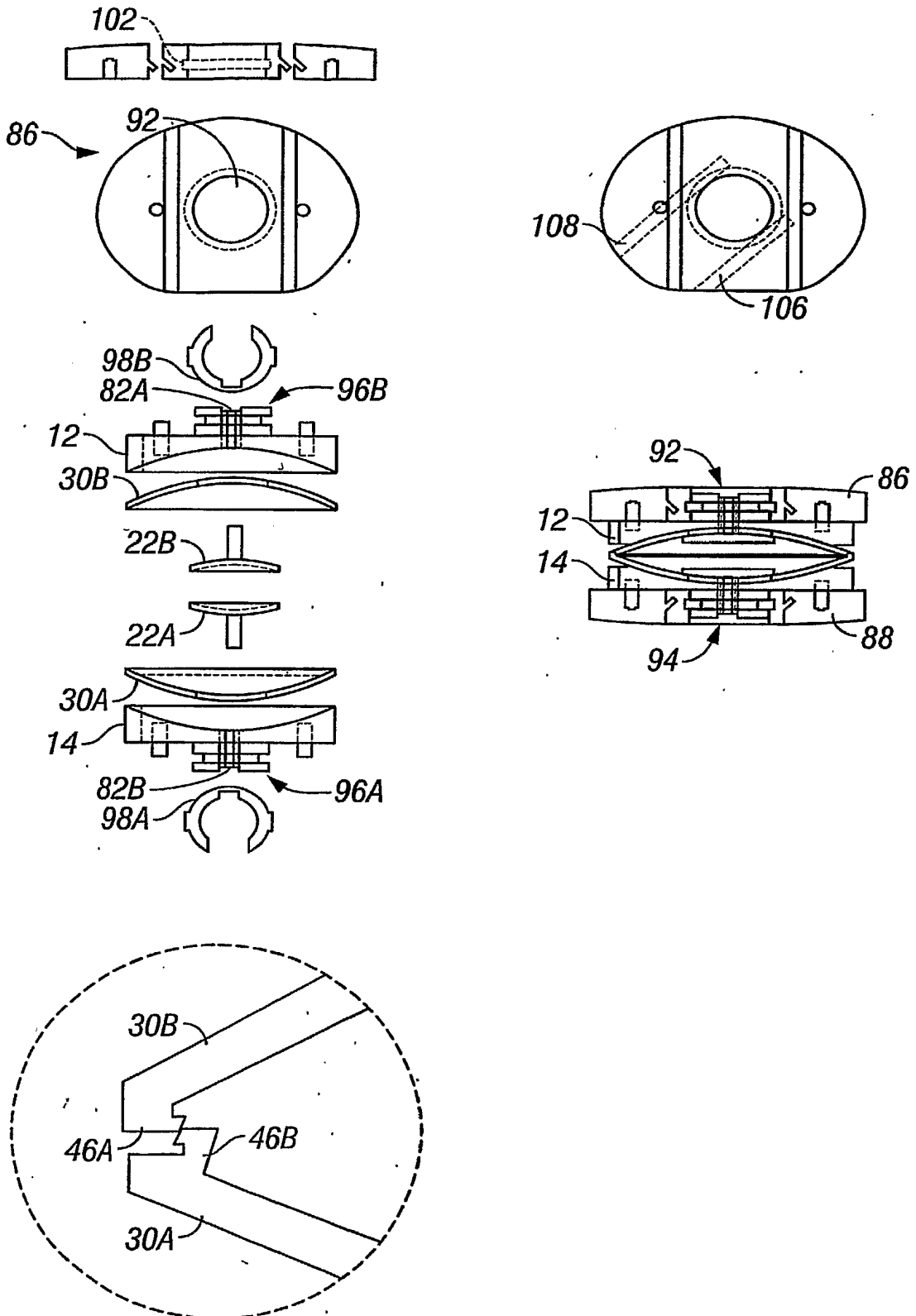


FIG. 10

SUBSTITUTE SHEET (RULE 26)

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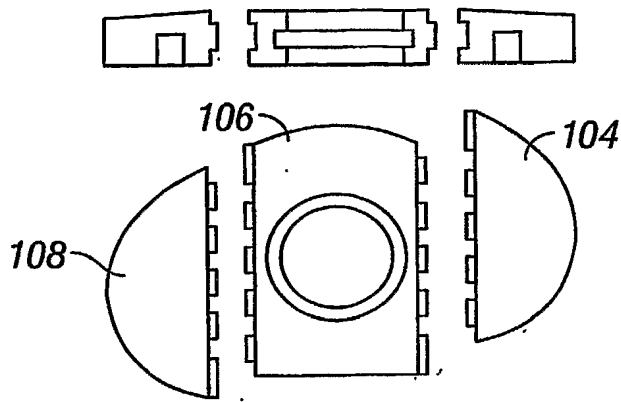


FIG. 11A

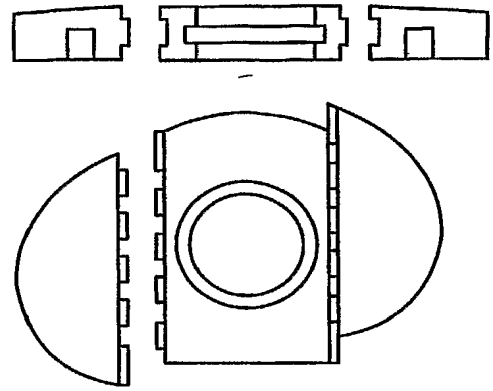


FIG. 11B

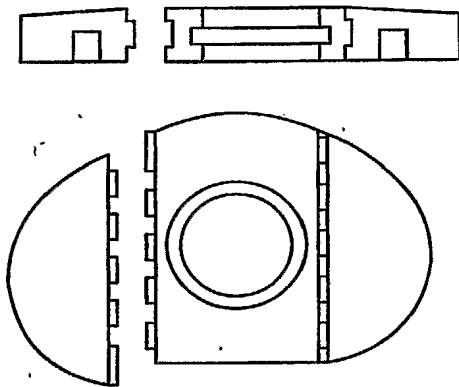


FIG. 11C

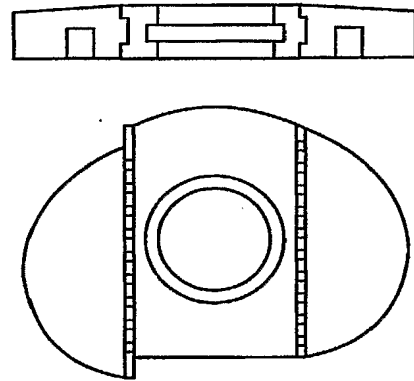
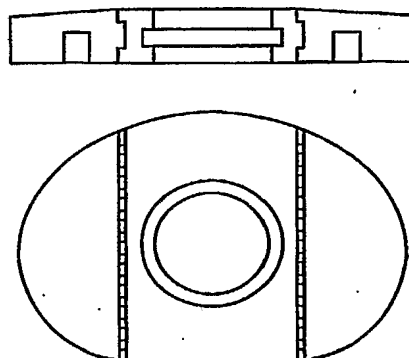


FIG. 11D



SUBSTITUTE FIG. 11E (RULE 26)

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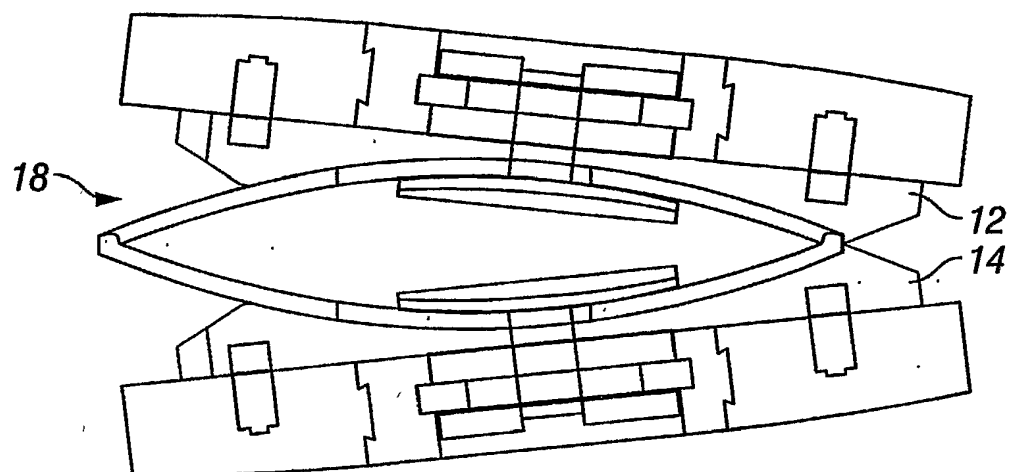


FIG. 12A

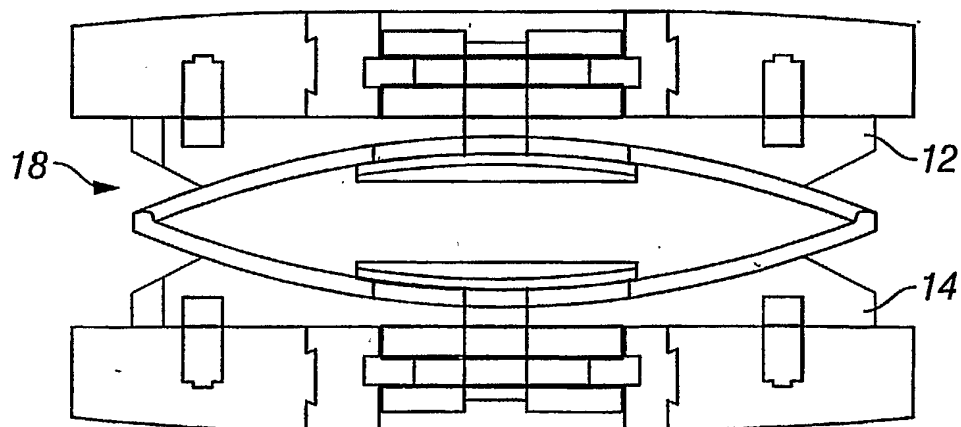
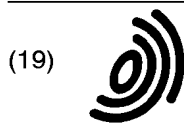


FIG. 12B



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(54) **Intervertebral disc allowing translational motion**

(57) A prosthetic vertebral endplate (31) has an outer surface (33) adapted to mate with a vertebral body, and an inner surface (35) having a first opening (34) thereon. A body portion (43) connects the inner (35) and outer surfaces (33) and defines a sidewall having a sec-

ond opening (37) thereon. The endplate (31) includes an articulation surface (41) suitable for supporting articulation motion. The first and second openings (34,37) communicate to form a channel (39) having a first open end.

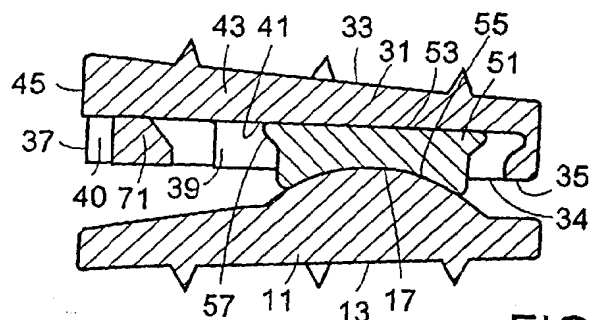


FIG. 1B

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Description

[0001] The leading cause of lower back pain arises from rupture or degeneration of lumbar intervertebral discs. Pain in the lower extremities is caused by the compression of spinal nerve roots by a bulging disc, while lower back pain is caused by collapse of the disc and by the adverse effects of articulation weight through a damaged, unstable vertebral joint. One proposed method of managing these problems is to remove the problematic disc and replace it with a prosthetic disc that allows for the natural motion between the adjacent vertebrae ("a motion disc").

[0002] US-6368350 ("Erickson") discloses a three-piece motion disc providing two articulation surfaces. The disc comprises a first piece having a curved surface, a second piece having a flat surface, and an intermediate piece having a corresponding curved articulation surface and a corresponding flat articulation surface. In many embodiments, the translation freedom of the intermediate piece is limited by a raised lip integrally formed around the edge of a flat surface upon the lower piece. Erickson teaches that the overall height of the device is varied by increasing or decreasing the thickness of one or more of the first, second or intermediate pieces. Erickson teaches that known methods for insertion of intervertebral prosthetic devices can be used for insertion of its device. Lastly, Erickson teaches that a variety of materials can be selected as materials of construction for the components of its device, including metals, polymers, and ceramics, and specifically teaches preferred combinations including metal-metal or metal-plastic combinations.

[0003] In each of Erickson's embodiments having a peripheral raised lip, the height of the core member appears to exceed the distance between the peripheral raised lips of the opposing endplates. Accordingly, the core member can not be inserted between the prosthetic endplates without overdistracting the disc space.

[0004] Erickson does not teach an open ended channel for inserting the intermediate piece between the prosthetic endplates, nor an additional component for retaining the intermediate piece upon the flat surface. Erickson does not teach piecemeal insertion of the device into the disc space. Erickson does not teach a metal-ceramic articulation interface.

[0005] US-5676701 ("Yuan") discloses, in one embodiment, a motion disc having a single articulation surface. This device includes a first component whose inner surface comprises a concave inner portion having a 360° circumference and a convex peripheral portion, and an opposing second component whose inner surface comprises a conforming convex inner portion and a convex peripheral portion. The convex/concave contours of the opposing inner portions forms a ball-and-socket design that allows unrestricted pivotal motion of the device, while the opposing convex peripheral contours allow flexion/extension bending motion in the

range of about 20-30°.

[0006] In another embodiment, Yuan discloses a device having two articulation interfaces, wherein one of the above-mentioned components is made in two pieces having opposing flat surfaces that form a translation interface to further provide the prosthetic with a certain amount of translation. See FIG. 9 of Yuan. Yuan discloses that the translation-producing pieces can be fitted together mechanically, via shrink-fit, or by welding methods.

[0007] However, Yuan does not disclose an open-ended channel for fitting the translation producing pieces.

[0008] US-5507816 ("Bullivant") discloses a three-piece motion disc providing two articulation interfaces and comprises an upper piece having a flat lower surface, a middle spacer having a flat upper surface and a convex lower surface, and a lower piece having a concave upper surface. The articulating convex and concave surfaces form an articulating interface that allows pivotal motion, while the flat surfaces form a translation interface that allows translational motion. Bullivant further teaches that the natural tension of the vertebrae ensures that the vertebrae are biased together to trap the spacer in place, and that the 90° extension of the convex and concave surfaces virtually eliminates any chance of the spacer escaping from between the plates under normal pivotal movement of the vertebrae.

[0009] The Bullivant device does not possess any channel for retaining the middle spacer within the device. Accordingly, it is prone to disengagement.

[0010] In each of the Erickson, Yuan, and Bullivant designs, the core member has a flat translation surface and a curved articulation surface.

[0011] There are currently two primary competitive artificial disc replacement devices on the market that are designed for the lumbar spine.

[0012] The first device has two articulation interfaces and comprises three components: an inferior endplate, a superior endplate, and a core. Both the inferior and superior endplates are metal and have raised bosses with concave spherical surfaces in the centre. The core is plastic and has convex surfaces on both the top and bottom which are surrounded by raised rims.

[0013] However, this device does not have an open ended channel for inserting the core between the endplates. Related devices are disclosed in US-4759766, US-5401269, and US-5556431.

[0014] In each of the devices disclosed in these documents, the core member has either two concave surfaces or two convex surfaces.

[0015] The second device has a single articulation interface and comprises three components: an inferior endplate, a superior endplate, and a plastic insert. The inferior endplate functions as a baseplate and has a sidewall forming an open ended channel for reception of the insert. The inner surface of the inferior endplate provides only stationary support for the insert and does

not have a motion surface. Since the plastic insert is designed to be locked securely into place within the inferior endplate, the inferior surface of the insert is not a motion surface. The superior surface of the insert includes articulation surface for articulation with the superior endplate. The superior endplate has an inferior articulation surface that articulates with the superior motion surface of the plastic insert, and a superior surface designed for attachment to a vertebral endplate. A related device is disclosed in US-5314477.

[0016] The second device does not have two articulation surfaces. The second device relies upon downward-extending flexible tabs disposed upon the insert to keep the insert within the open-ended channel. These tabs eliminate any ability for the insert to translate with the adjacent endplate surfaces.

[0017] FR-A-2730159 ("Germain") discloses a motion disc in which the core member has one convex and concave surface. Germain further teaches that the radius of the upper curved surface (3a) of the core member is less than the radius of the lower curved surface (3b) of the core member.

[0018] Therefore, there is a need for a motion device having two articulation interfaces that allows for initial insertion of the prosthetic endplates into the disc space and then insertion therebetween of a core member having two articulation surfaces.

[0019] The present invention provides a motion disc having two articulation interfaces and an open ended channel. The two articulation interfaces allow the motion disc to more fully restore the natural motion of the spine than would a single articulation interface. The open ended channel allows for initial insertion of the prosthetic endplates into the disc space and then insertion therebetween of a core member having two articulation surfaces, thereby lessening the extent of required overdistraction.

[0020] Therefore, in accordance with the present invention, there is provided a prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a vertebral body,
- ii) an inner surface having a first opening thereon,
- iii) a body portion connecting the inner and outer surfaces and defining a sidewall comprising a second opening thereon, and
- iv) an articulation surface suitable for supporting articulation motion,

wherein the first and second openings communicate to form a channel having a first open end.

[0021] Also in accordance with the present invention, there is provided an intervertebral motion disc comprising:

- a) a prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a vertebral body,
- ii) an inner surface having a first opening thereon,
- iii) a body portion connecting the inner and outer surfaces and defining a sidewall comprising a second opening thereon, and
- iv) a first articulation surface suitable for supporting articulation motion.

wherein the first and second openings communicate to form a channel having a first open end, and

- b) a core member having a first articulation surface suitable for supporting articulation motion,

wherein the core member is disposed within the channel and oriented therein to produce a first articulation interface between the first articulation surface of the first endplate and the first articulation surface of the core member.

[0022] The disc of the present invention is superior to that of Erickson, Yuan and the first commercial device in that the core member can be inserted through the open ended channel, thereby allowing for initial insertion of the prosthetic endplates into the disc space and then insertion therebetween of a core member having two articulation surfaces through the channel, and lessening the extent of required overdistraction.

[0023] The disc of the present invention is superior to that of Bullivant in that the channel helps retain the core member between the endplates and so need not rely upon natural ligament tension to retain the core member between the endplates, and prevents excessive lateral motion of the core.

[0024] The disc of the present invention is superior to that of the second commercial device in that its two articulation interfaces allow the motion disc to restore the natural motion of the spine more fully than would a single articulation interface.

[0025] Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

FIGS. 1a-1c show isometric, cross-sectional and front views of a first embodiment of the present invention.

FIGS. 2a-2d show isometric, cross-sectional, front and elevated views of the inferior endplate of the first embodiment of the present invention.

FIGS. 3a-3c show isometric, elevated and front views of the superior endplate of the first embodiment of the present invention.

FIGS. 4-6 show embodiments cross-sectioned through the channel of an endplate.

FIGS. 7a-7c show isometric, cross-sectional and front views of the core member of the first embodiment of the present invention.

FIG. 8 shows a cross-section of an embodiment of the present invention in which the core member has a non-articulating projection.

FIG. 9 shows a cross-section of an embodiment of the present invention in which the core member has two non-articulating projections.

FIG. 10 shows a cross-section of an embodiment of the present invention in which the core member has an articulating projection.

FIG. 11 shows a cross-section of an embodiment of the present invention which defines distances.

FIG. 12 shows a cross-section of an embodiment of the present invention in which the translation surface is hemi-cylindrical.

FIG. 13 shows a side view of a core member having a spring portion.

FIG. 14 shows a side view of a core member having a helical recess therein.

FIGS. 15a-15b show isometric and elevated views of the locking tab of the first embodiment of the present invention.

FIG. 16 shows a locking tab adapted for engagement with a vertebral body.

FIG. 17 shows an elevated view of an endplate, core and tab, wherein the inner surface of the tab has an elongated portion.

FIG. 18 shows a cross-section of a superior endplate having a sunken channel.

FIG. 19 shows a first endplate having a horizontally-extending projection and a core member having a recess for mating with the projection.

FIGS. 20a-20c show isometric, elevated, and cross-sectional views of an embodiment of the present invention in which the core member has a significantly convex articulation surface and a substantially flat articulation surface.

FIGS. 21a-21b shows a front and a cross-sectional view of another embodiment of the present invention having a slightly curved articulation interface running the anterior-posterior direction.

FIGS. 22a-22b shows a front and a cross-sectional view of another embodiment of the present invention having a slightly curved articulation interface running the medial-lateral direction.

FIG. 23 shows an isometric view of a prosthetic vertebral endplate of the present invention having a channel having two open ends.

FIG. 24 shows an isometric view of the present invention in which a locking tab comprises first and second arms, and each arm is shaped to be secured to the endplate in a recess formed in the lateral wall portions of the endplate.

FIG. 25 shows an isometric view of the present invention in which one endplate is adapted to receive a screw for fixation to an adjacent vertebra.

[0026] For the purposes of the present invention, "prosthetic vertebral endplate" broadly describes a com-

ponent designed to substantially fit within an intervertebral space and mate with an opposing surface of one of the adjacent vertebral bodies. The "prosthetic vertebral endplate" includes all geometric configurations, including but not limited to substantially thin and substantially blocky configurations. Types of mating include, but are not limited to, penetrating the adjacent vertebral body, simply contacting the adjacent vertebral body, and providing fixation through a third component such as a fastener (such as a screw) that is received within or connected to the prosthetic vertebral endplate. Such fixation may occur upon a non-opposing surface of the adjacent vertebral body (such as the anterior wall of the vertebral body). The adjacent vertebral body may be prepared or unprepared so that the contacting surface thereof may include the cortical end endplate portion of the vertebral body or the internal cancellous portion of the vertebral body.

[0027] For the purposes of the present invention, a "substantially curved articulation interface" produces substantially pivotal motion during articulation. Examples of such substantially curved interfaces include but are not limited to hemispherical interfaces having a radius of between about 10 mm and about 30 mm.

[0028] For the purposes of the present invention, both "slightly curved articulation interfaces" and "substantially flat articulation interfaces" produce substantially translational motion during articulation. Examples of such "slightly curved interfaces" include but are not limited to hemispherical interfaces having a radius of between about 40 mm and about 100 mm. For the purposes of the present invention, a "substantially flat articulation interface" is sufficiently flat so as to allow axial rotation of either mating component at any point along the interface.

[0029] Now referring to FIG. 1, there is provided a motion disc 1 comprising:

a) a first prosthetic vertebral endplate 31 comprising:

- i) an outer surface 33 adapted to mate with a first vertebral body,
- ii) an inner surface 35 having a first opening 34 thereon and a first articulation surface 41,
- iii) a body portion 43 connecting the inner and outer surfaces and defining a sidewall 45 comprising a second opening 37 thereon,

b) a second prosthetic vertebral endplate 11 comprising:

- i) an outer surface 13 adapted to mate with a second vertebral body, and
- ii) an inner surface 15 comprising a first articulation surface 17,

c) a core member 51 comprising:

- i) a first articulation surface 53 adapted for articulation with the first articulation surface of the first endplate, and
- ii) a second articulation surface 55 adapted for articulation with the first articulation surface of the second endplate,

wherein the first and second openings communicate to form a channel 39 having a first open end 40, and

wherein the core member is disposed within the channel and oriented therein to produce a first articulation interface between the first articulation surface of the first endplate and the first articulation surface of the core member, and a second articulation interface between the first articulation surface of the second endplate and the second articulation surface of the core member.

[0030] The motion disc of FIG. 1 further comprises means for limiting the translation of the core member. In FIG. 1, the means comprises a locking tab 71 that is adapted to securely lock into place after the core has been inserted and to help retain the core within the channel.

[0031] Now referring to FIG. 1, in some embodiments, the device comprises four main components: an inferior endplate 11, a superior endplate 31, a core member 51, and a locking tab 71. In one preferred embodiment, the inferior endplate comprises a substantially convex surface 17 that is designed to conform to and mate with a substantially concave surface 55 formed in the core member. The superior endplate has an open channel 39 within which substantially flat lower articulation surface 41 is disposed. The substantially flat lower articulation surface 41 is intended to mate with the substantially flat upper articulation surface 53 of the core member. Channel 39 is designed to retain the core and prevent its lateral expulsion. The core member comprises a substantially concave bottom articulation surface 55 and a substantially flat top articulation surface 53, each of which is designed to mate with the corresponding surfaces on the endplates to form articulation interfaces. Preferably, the articulation interfaces are conforming. In addition, the core member is designed with a retaining feature 57 that mates with a corresponding undercut formed in the sidewall, thereby promoting its retention within the superior endplate channel. Lastly, the locking tab 71 is designed to effectively close the open end of the channel once the core member has been inserted, thereby promoting retention of the core.

[0032] In other embodiments, the features on the superior and inferior endplates can be reversed. For example, the substantially flat articulation surface of the superior endplate could be provided upon the inferior endplate, and the substantially curved surface of the inferior endplate could be provided on the superior endplate. In addition, the placement of the ball and socket-

like substantially curved surfaces could be reversed so that the core member has a substantially convex articulation surface and the corresponding endplate has a matching substantially concave articulation surface. The substantially flat articulation surfaces may also be modified to be slightly curved and still provide substantially translational motion. Lastly, additional components such as screws for initial fixation of the implant may be added to the design.

[0033] Each of the four main components of one preferred embodiment will now be described in more detail:

[0034] Now referring to FIG. 2, in one embodiment, inferior endplate 11 has an inferior surface 13 designed to mate with a natural vertebral endplate, a superior surface 15 designed to mate with both instrumentation and the core member, and a body portion 16 therebetween. The periphery of the inferior endplate comprises an anterior wall 21, a posterior wall 23, and sidewall portions 25 and 27.

[0035] Preferably, the inferior (outer) surface 13 of this endplate is either flat, curved or domed to match the natural vertebral endplate. Alternatively, the geometry of the inferior surface can be designed so that it will match the shape of the patient's vertebral endplate after the vertebral endplate has been modified by an endplate-shaping instrument. In addition, the inferior surface of this endplate can further comprise features to promote and secure initial fixation and bony ingrowth including, but not limited to, spikes, keels, teeth, projections (such as dovetails), recesses (such as grooves) and porous coatings.

[0036] Superior (inner) surface 15 comprises a peripheral portion 9 and a raised inner portion 7 extending substantially from the middle of the peripheral portion. This raised inner portion comprises a raised surface 5, a sloped anterior wall 3, and a pair of raised sidewalls 2,4.

[0037] Extending from the raised surface of the superior surface of the inferior endplate is a highly polished substantially convex articulation surface 17 designed to mate with a corresponding substantially concave articulation surface (not shown) disposed upon the core member. Preferably, substantially convex articulation surface 17 is further designed to conform to the corresponding concave articulation surface. In the preferred embodiment the articulation surface 17 is convex. However, the substantially curved articulation surface can also be concave if desired to mate with a corresponding substantially convex articulation surface (not shown) disposed upon the core member. Preferably, the substantially curved articulation surface 17 has been polished to a surface roughness Ra of no more than 10 nm.

[0038] Preferably, formed upon each raised sidewall is a slotted guide rail 60 running substantially along the length of each raised sidewall. For the purposes of the present invention, a slot is a longitudinally-extending recess in a first surface having a continuous opening onto a second lateral surface along at least a portion of its

longitudinal axis. In contrast, a hole is closed about its periphery along its longitudinal axis and so does not open onto a second lateral surface. In some embodiments particularly suited for anterior approaches, the rails run in an anterior-posterior direction. These two guide rails are designed to mate with instrumentation used during the surgical procedure, and optionally with additional implant components (such as a revision spacer or a locking tab). When used as guide rails, slots formed in the raised side walls are more advantageous to holes running through the raised portion because a hole disposed near the edges of the raised portion would be prone to failure and so additional material would be required to support the raised sidewall. In preferred embodiments, the inner surface of the slot is angled. Without wishing to be tied to a theory, it is believed that angled slots are often selected over square slots because a square slot disposed near the edges of the raised portion is prone to failure and so additional material is required to support the raised sidewall. Preferably, the guide rails are located within the footprint of the disc formed by the side wall portions 25 and 27 of the endplates.

[0039] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first motion segment comprising:

- i) an outer surface adapted to mate with a first vertebral body,
- ii) an inner surface comprising a first articulation surface,
- iii) a front and a back wall between the inner and outer surfaces, and
- iv) a pair of slots formed in the first motion segment, each slot running substantially from the front wall and opening onto the front wall,

b) a second motion segment comprising:

- i) an outer surface adapted to mate with a second vertebral body,
- ii) an inner surface comprising a first articulation surface, and

wherein the articulation surfaces are adapted to produce an articulation interface.

[0040] In other embodiments particularly suited for translateral approaches, the rails run at a substantial angle to the anterior-posterior direction. Typically, this substantial angle is between about 30° and about 60° from the anterior-posterior direction.

[0041] Now referring to FIG. 3, superior endplate 31 has a superior outer surface 33 designed to mate with the vertebral endplate, an inferior inner surface 35a and 35b that is designed to mate with both instrumentation and the core member, and a body portion 43 therebe-

tween defining a plurality of sidewalls, including an anterior wall 45, a posterior wall 46, and lateral wall portions 47 and 48.

[0042] Preferably, the superior outer surface 33 of this endplate is either flat, curved or domed to match the natural vertebral endplate. Alternatively, the geometry of the superior surface can be designed so that it will match the shape of the patient's vertebral endplate after the vertebral endplate has been modified by an endplate-shaping instrument. In addition, the superior surface of this endplate can further comprise features to promote secure initial fixation and bony ingrowth including, but not limited to, spikes, keels, teeth, projections (such as dovetails), recesses (such as grooves) and porous coatings.

[0043] Now referring also to FIG. 1, channel 39 is formed from the communication of the second opening 37 in the anterior wall with the first opening 34 formed on inner surface 35a of this endplate. In this embodiment, the channel has i) a substantially flat articulation surface 41 that provides linear translation and is designed to mate with a corresponding substantially flat articulation surface of the core member and ii) a sidewall 50 surrounding three sides of the substantially flat articulation surface. Preferably, substantially flat articulation surface 41 is further designed to conform to a corresponding substantially flat articulation surface of the core member. In some embodiments, the substantially flat articulation surface 41 may be replaced with a slightly curved articulation surface. Preferably, the substantially flat articulation surface has been polished to a surface roughness Ra of no more than 10 nm. The channel has a width adapted to receive and retain the core. Preferably, the channel has a shape that allows the core to be easily inserted therein and then retained therein by a means for limiting translation. In the preferred embodiment, the sidewall 50 of the channel has an angular undercut 46 formed therein that is designed to retain the core.

[0044] In some embodiments (as in FIG. 1), bottom surface 41 is substantially flat to provide substantially translational motion with a corresponding flat superior surface of the core member. However, in other embodiments, this bottom surface is slightly curved to provide not only substantially translational motion with a corresponding slightly curved superior surface of the core member, but also a soft resistance to extreme A-P translation of the core. Preferably, the slightly curved interface is hemicylindrical, preferably with the curve of the hemicylinder running in the anterior-posterior ("A-P") direction. In other embodiments, the curve of the hemicylinder runs in the medial-lateral ("M-L") direction, and so allows the use of a thicker core member.

[0045] The opened end channel of FIGS. 1 and 3 is believed to be novel in prosthetic intervertebral motion discs having an intermediate component disposed between a pair of prosthetic vertebral endplates. The open end of the channel is advantageous in that it allows the

surgeon to insert only the upper and lower plates into the disc space, and then insert the intermediate piece through the open end of the channel. Because the combination of the upper and lower endplates can be inserted with a lower profile than if the intermediate component were in place, there is a lesser need to severely overdistraction or otherwise harm the opposing natural vertebral endplates. The substantially translational articulation capability provided by the first articulation interface allows the disc to more nearly imitate the natural motion of an intervertebral disc.

[0046] Therefore, in accordance with the present invention, there is provided a method of implanting an intervertebral motion disc, comprising the sequential steps of:

- inserting into a disc space a partial motion disc comprising:
 - a) a first prosthetic vertebral endplate comprising:
 - i) an outer surface adapted to mate with a first vertebral body, and
 - ii) an inner surface comprising a first motion surface,
 - b) a second prosthetic vertebral endplate comprising:
 - i) an outer surface adapted to mate with a second vertebral body,
 - ii) an inner surface comprising an opening forming a channel comprising opposing side walls, a first open end and a second motion surface, and
- inserting into the open end of the channel a core member comprising:
 - i) a first surface adapted for motion with the first motion surface, and
 - ii) a second surface adapted for motion with the second motion surface,

wherein the core member is disposed within the channel and oriented therein to provide a first motion with the first motion surface and a second motion with the second motion surface.

[0047] In some embodiments, now referring to FIG. 4, the channel comprises a sunken anterior surface 203 and a raised posterior articulation surface 205. Because these surfaces occupy different levels, the raised posterior portion can now be more easily polished. In some embodiments, the transition between these surfaces defines a ledge 207. This ledge acts as a stop against overinsertion of the tab, thereby preserving the high polish of the raised posterior articulation surface, and

eases insertion of the core.

[0048] In some embodiments, now referring to FIG. 5, the anterior surface 211 is ramped to rise posteriorly. This embodiment also minimizes the necessary polishing of the articulation surface. As the tab moves up the ramp, the combined action of the elevation rise and the elevation limit provided by the undercut dovetail 213 of the sidewall acts as a stop upon the further posterior movement of the tab.

[0049] When the patient is standing in a supine position, the natural loads upon the spine are such that the core member is most preferably positioned in the posterior portion of the motion disc, as in FIG. 1, and more preferably between about 60-80% towards the posterior. When the patient first bends forward, the core member may move anteriorly or posteriorly. If the core moves anteriorly, when the patient returns to a supine position, the substantially flat nature of the channel of FIG. 1. does not help the core member move back to its original posterior position.

[0050] Therefore, in some embodiments, now referring to FIG. 6, at least a portion of the channel is ramped to slope downward posteriorly. The channel of FIG. 6 comprises an anterior articulation surface having a downward sloping ramp 221. If the core is disposed in an anterior portion of the channel, the non-parallel nature of the bearing surfaces will urge the core to move back to its original posterior position when the patient returns to an erect position.

[0051] Therefore, in accordance with the present invention, there is provided a prosthetic vertebral endplate, comprising:

- i) an outer surface adapted to mate with a first vertebral body to define a first attachment plane substantially parallel to the vertebral body endplate, and
- ii) an inner surface comprising a substantially flat motion surface,

wherein the substantially flat motion surface and the first attachment plane define an angle α .

[0052] In one preferred embodiment, the angle α of the ramp is between about 10° and about 30°.

[0053] When the channel of the present invention contains a substantially flat articulation surface, overdistraction caused by insertion of the core member is desirably minimized. However, in other embodiments, the channel may include a slightly curved surface which rises anteriorly and/or a flat surface having an anteriorly-disposed lip having a height less than that of sidewalls. Since the lip or slightly curved surface may desirably retain the core member within the channel, it is contemplated that such a lip may obviate the need for another translation-limiting component such as a tab that prevents expulsion of the core while still providing a height reduction benefit that lessens the need for overdistraction. Preferably, this lip has a height that is no more than

80% of the channel depth, more preferably no more than 50%, more preferably no more than 25%.

[0054] Referring again to FIG. 3, formed in each side-wall 47, 48 is a recessed guide rail 49. Guide rail 49 begins at the anterior wall, extends across each side-wall, and ends at the posterior wall. These two guide rails correspond to the two guide rails 60 of the inferior plate.

[0055] Now referring to FIG. 7, the core member 51 comprises a body portion 52 forming a substantially flat superior surface 55 that is designed to articulate with the bottom surface of the superior endplate and a substantially curved inferior surface 53 that is designed to mate with the inferior endplate. In some preferred embodiments, the body portion has a substantially cylindrical body portion 52. In some preferred embodiments, the body portion has a substantially rectangular body portion 52. Preferably, superior surface 55 is further designed to conform to the bottom surface 41 of the superior endplate. Also preferably, substantially curved inferior surface 53 is designed to conform with a corresponding substantially curved upper surface of the inferior endplate. In some embodiments (as in FIG. 7), superior surface 55 is substantially flat to provide substantially translational motion with a corresponding flat bottom surface of the superior endplate. However, in other embodiments, superior surface 55 is slightly curved to provide substantially translational motion with a corresponding curved bottom surface of the superior endplate as well as soft resistance to extreme translational motion.

[0056] The substantially curved inferior surface can be any shape designed for pivotal articulation, including hemispherical, hemicylindrical, hemi-ellipsoidal, and oblong. However, in preferred embodiments, the curved surface is hemi-spherical. In the preferred embodiments, the substantially curved inferior articulation surface of the core is concave. However, the curved articulation surface can also be convex, if desired, to mate with a corresponding substantially concave articulation surface disposed upon an endplate.

[0057] The substantially flat superior surface may be modified to any slightly curved geometry that allows at least one degree of substantially translational motion, including a hemi-cylindrical shape.

[0058] In addition to the two articulation surfaces, the core has a peripherally disposed retaining feature 57 that is designed to prevent the core from accidentally dislocating from the implant. The shape of the retaining feature is adapted to fit a complementary feature (46 of FIG. 3) in the sidewall of the retaining channel. In this embodiment, the retaining feature 57 extends from the cylindrical body portion. In a preferred embodiment, the retaining feature is an angled flare disposed near the end of the core having the substantially translational surface. However, in other embodiments, the retaining feature can be a recess extending into the body portion 52.

[0059] Typically, the core of a conventional motion

disc has either two convex surfaces or two concave surfaces. The Germain motion disc is the only motion disc known to the present inventors in which the core comprises one convex motion surface and one concave motion surface. However, Germain further requires the radius of the upper surface to be smaller than the radius of the lower motion surface. Without wishing to be tied to a theory, because of this requirement, the Germain disc may suffer from a high centre of rotation.

[0060] In an effort to overcome these deficiencies, in some embodiments of the present invention, the radius of the upper surface of the core is greater than the radius of the lower motion surface. Without wishing to be tied to a theory, this embodiment of the present invention may possess an advantage of a low centre of rotation.

[0061] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) an upper prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with an upper vertebral body,
- ii) an inner surface having a first articulation surface,

b) a lower prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a lower vertebral body, and
- ii) an inner surface having a first articulation surface, and

c) a core member comprising:

- i) an upper articulation surface adapted for articulation with the first articulation surface of the upper endplate and having a radius, and
- ii) a lower articulation surface adapted for articulation with the first articulation surface of the lower endplate and having a radius,

wherein the core member is disposed between the endplates and oriented therein to produce an upper articulation interface between the first articulation surface of the upper endplate and the upper articulation surface of the core member, and a lower articulation interface between the first articulation surface of the lower endplate and the lower articulation surface of the core member, and

wherein the radius of the upper articulation surface of the core member is greater than the radius of the lower articulation surface of the core member.

[0062] Preferably, the radius of the upper motion surface of the core is at least three times greater than the radius of the lower motion surface of the core, more preferably between 3 and 5 times greater. Preferably, the

radius of the upper surface of the core is between about 40 mm and about 100 mm, and the radius of the lower motion surface is between about 10 mm and about 30 mm.. Preferably, the radius of the upper surface of the core is between 40 mm and 80 mm. Below 40 mm, the depth of the curve requires adding significantly more material to the corresponding endplate, thereby increasing the height of the implant. Above 80 mm, the curve provides a less significant braking.

[0063] Typically, the core of a conventional motion disc has either one flat surface and one curved surface (as in Erickson, Yuan and Bullivant), two cylindrical surfaces (as in Charite '766), or two hemispherical surfaces (as in Germain). However, a substantially flat surface in a motion disc does not resist extreme movement of the core. Motion discs having two hemicylindrical surfaces can not provide the desired pivotal movement over 360°. Motion discs having two hemispherical surfaces do not allow for the easy correction of misaligned endplates.

[0064] In an effort to overcome these deficiencies, in some embodiments of the present invention, the core of the present invention has one hemispherical surface and one non-hemispherical curved surface. Preferably, the non-hemispherical curved surface is hemicylindrical. In this condition, the hemispherical surface provides the pivotal rotation freedom found in the natural disc, while the linear dimension of the hemicylindrical surface (when provided in the medial-lateral direction, as in FIGS. 12 and 22a) provides substantially translational movement in a first direction (thereby providing easy correction of misaligned endplates), and curved dimension of the hemicylindrical surface provides some resistance against extreme movement in a second direction.

[0065] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a first vertebral body,
- ii) an inner surface having a first articulation surface,

b) a second prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a second vertebral body, and
- ii) an inner surface having a first articulation surface, and

c) a core member comprising:

- i) a first articulation surface adapted for articulation with the first articulation surface of the first endplate, and

- ii) a second articulation surface adapted for articulation with the first articulation surface of the second endplate,

wherein the core member is disposed between the endplates and oriented therein to produce a first articulation interface between the first articulation surface of the first endplate and the first articulation surface of the core member, and a second articulation interface between the first articulation surface of the second endplate and the second articulation surface of the core member, and

wherein the first articulation surface of the core member is spherical and the second articulation surface of the core member is curved and non-spherical.

[0066] Also in accordance with the present invention, there is provided a core member for articulation between first and second prosthetic vertebral endplates, comprising:

- 1. a first articulation surface adapted for articulation with a first articulation surface of the first prosthetic vertebral endplate, and
- 2. a second articulation surface adapted for articulation with the first articulation surface of the second prosthetic vertebral endplate,

wherein the first articulation surface is a portion of a sphere and the second articulation surface is a portion of a curved, non-spherical shape.

[0067] Preferably, the non-spherical curved surface is a hemicylindrical surface, as such a surface that can articulate with a similar opposing hemicylindrical surface and provide conforming articulation. Also preferably, the curved dimension of the hemicylindrical surface is provided in the A-P direction (to provide a soft braking) while the linear dimension is provided in the medial-lateral direction. However, in other embodiments, the curved dimension of the hemicylindrical surface is provided in the medial-lateral direction, while the linear dimension is provided in the anterior-posterior direction.

[0068] Also preferably, the hemispherical surface is substantially curved and the curved, non-hemispherical surface is slightly curved.

[0069] In the embodiment of FIG. 3, because the translational articulation surface 41 that mates with the core member is disposed within the channel, both the core retention function and translation surface function of this endplate are provided by the same surface within the channel. However, in other embodiments, the core retention function and translation surface function can be provided by separate surfaces. For example, now referring to FIG. 8, there is provided a motion disc wherein the core member has a projection 501 that extends only partially into channel 503. The channel and projection elements of this device function merely to limit the lateral translational freedom of the core member. In this embodiment, the bottom of the channel does not have to

be adapted to support articulation motion. Rather, substantially flat articulation surface 505 provided on the inner surface of the endplate forms an articulation interface with the substantially flat articulation surface 507 of the core member.

[0070] Similarly, in FIG. 9, there is provided a prosthetic vertebral endplate 551 having two channels with an articulation surface therebetween. In particular, endplate 551 comprises an inner surface 552 having first 553 and second 555 channels formed therein, and an articulation surface 567 formed between the channels. The channels begin at the anterior wall 557 of the endplate and terminate prior to opening onto the posterior wall (not shown) of the endplate. Core member 561 comprises first 563 and second 565 projections and an articulation surface 569 therebetween, each projection having a shape that mates with its corresponding channel to limit the medial-lateral translation of the core member. Anterior-posterior translation is accomplished by the mating of articulation surface 569 of the core and articulation surface 567 of the endplate to produce an articulation interface. Expulsion of the core member of this embodiment can be prevented by any number of means. For example, after the core member is slid into the channels, locking tabs can be inserted into the anterior end of each channel. Alternatively, the intermediate portion 567 of the inner surface can comprise at least one flexible tab that allows the passage of the core member towards the posterior portion of the endplate, but prevents its passage back out.

[0071] In other embodiments, the core member and superior endplate can be adapted to provide more than one articulation interface. Now referring to FIG. 10, the bottom surface 511 of the projection is polished and extends sufficiently into the channel to bear upon the bottom surface 513 of the channel to form a first articulation interface, while an articulation surface 515 is also provided on the inner surface of the endplate to form a second articulation interface with a second articulation surface 517 of the core member.

[0072] Likewise, in FIG 9, projections 563, 565 may optionally mate with the bottom surfaces of the channels to form additional articulation interfaces.

[0073] In preferred embodiments, the core member is adapted to provide pivotal motion with a first endplate. Preferably, the pivotal motion is provided by the corresponding substantially curved surfaces of the core member and a first endplate. More preferably, the curved surfaces are conforming. More preferably, the conforming curved surfaces are selected from the group consisting of hemispherical and hemicylindrical surfaces. Still more preferably, the conforming curved surfaces are hemispherical surfaces.

[0074] In preferred embodiments, the core member is adapted to provide at least one degree of translation motion with a second endplate. Preferably, the at least one degree of translation motion is provided by corresponding substantially flat planar surfaces of the core member

and a second endplate. Now referring to FIG. 11, in some embodiments, exactly one degree of translation motion is achieved by sizing the core member so that its diameter D_c equals the width W of the channel in which it is disposed. In this case, the one degree of freedom is translation in the A-P direction. Now referring to FIG. 10, in other embodiments, one degree of translation motion is realized by sizing a projection upon the core member so that the diameter of the projection D_p equals the width W of the channel in which it is disposed. Preferably, the motion provided by the one-degree-of-freedom embodiment is in the anterior-posterior direction. In other embodiments, more than one degree of freedom may be realized by sizing the core member so that its diameter (or the diameter of its projection that bears upon the articulation surface) is smaller than the width W of the channel, thereby allowing the core to move laterally as well.

[0075] In other embodiments, as in FIG. 12, one degree of translation motion is realized by providing a channel having a hemicylindrical surface 701 and a core member having a corresponding hemicylindrical surface 703 to produce a hemicylindrical interface. In this particular embodiment, the core has a slightly convex hemicylindrical surface adapted to provide translational motion in the A-P direction with the slightly concave hemicylindrical bottom surface of the channel.

[0076] The flat surfaces that provide translation movement in Erickson are either circular or elongated. However, in the circular embodiments, since there is very little medial-lateral movement in natural spinal movement, the circular designs of Erickson do not readily mimic the natural spinal movements. In the elongated embodiments, Erickson teaches that the elongated embodiment provides movement along only one axis. Accordingly, if an elongated (uniaxial) design of Erickson is selected, any misalignment of the components in the M-L axis can not be easily corrected by simple translation of this motion surface.

[0077] Therefore, in some embodiments, the core member and its slightly curved or substantially flat translation surface are adapted to provide a translation surface that provides for substantial movement in the A-P axis and lesser movement in the M-L axis. When this embodiment is selected, the device provides not only the degree of A-P movement that substantially mimics the A-P motion of the natural intervertebral disc but also a limited amount of M-L motion that allows the surgeon to use this interface to compensate for any surgical misalignment of the prosthetic vertebral endplates.

[0078] Therefore, in accordance with the present invention, there is provided intervertebral motion disc comprising:

- a) a first prosthetic vertebral endplate comprising:
 - i) an outer surface adapted to be attached to a first vertebral body, and

ii) an inner surface comprising a first articulation surface,

b) a core member comprising a first articulation surface,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface having a range of anterior-posterior A-P motion and a range of medial-lateral M-L motion, and

wherein the range of A-P motion is between 1.5 and 50 times greater than the range of M-L motion.

[0079] Preferably, the maximum range of A-P motion is between 1.5 and 50 times greater than the maximum range of M-L motion, more preferably between 1.5 and 8 times, more preferably between 4 and 8 times, more preferably between 5 and 7 times, and still more preferably between 5.5 and 6.5 times.

[0080] In some embodiments designed for use in the lumbar spine, the maximum range of A-P motion is between 2 and 5 mm, preferably between 3 and 4 mm, and the maximum range of M-L motion is between 0.25 mm and 2 mm, preferably between 0.25 mm and 1 mm.

[0081] Now referring to FIG. 11, in preferred embodiments, the channel is defined by a length L_{CH} and a width W_{CH} , the articulation surface portion of the channel is defined by a length L_{MS} and a width W_{MS} , and the core member is defined by a diameter D_{co} . As shown in FIG. 11, the length of the articulation surface does not include the space occupied by a tab T.

[0082] Preferably, the length of the articulation surface L_{MS} is between about 10% to about 50% greater than the diameter D_{co} of the core. When this range is achieved in typical geometries, the core member can move between about 1 mm and about 5 mm in the anterior-posterior direction. Within this range, the core member has translation capability that mimics typical anatomical anterior-posterior motion.

[0083] Preferably, the width of the channel W_{CH} is between about 5% and about 20% greater than the diameter D_{co} of the core. When this range is achieved in typical geometries, the core can move between about 0.5 mm and about 2 mm in the medial-lateral direction. This 0.5-2 mm of freedom may correct for misplacement of the pivotal articulation surface elements.

[0084] Preferably, when the channel has a closed end, the length of the channel L_{CH} extends to between about 60% to 80% the distance from the anterior wall to the posterior wall of the endplate. When this range is achieved, the core can reside substantially near the anatomically typical vertical axis of rotation.

[0085] In preferred embodiments, each of the inferior endplate, superior endplate and core member is manufactured from a material that possesses the strength and high wear resistance desired for use as a motion disc component.

[0086] These components of the present invention

may be made from any non-resorbable material appropriate for human surgical implantation, including but not limited to, surgically appropriate metals, and non-metallic materials, such as carbon fibre composites, polymers and ceramics.

[0087] If a metal is chosen as the material of construction for a component, then the metal is preferably selected from the group consisting of titanium, titanium alloys (such as Ti-6Al-4V), chrome alloys (such as CrCo or Cr-Co-Mo) and stainless steel.

[0088] If an articulation interface is formed from first and second metal articulation surfaces, then the components are preferably manufactured so that the grains of the first metal articulation surface are disposed substantially perpendicular to the grains of the second metal articulation surface grains of the first metal articulation surface.

[0089] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body, and
- ii) an inner surface comprising a first articulation surface comprising a first metal having grains oriented in a first direction, and

b) a core member comprising:

- i) a first articulation surface comprising a metal having grains oriented in a second direction,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface, and

wherein the first and second directions of grain orientation are not parallel.

[0090] If a polymer is chosen as a material of construction for a component, then the polymer is preferably selected from the group consisting of polyesters, (particularly aromatic esters such as polyalkylene terephthalates, polyamides; polyalkenes; poly(vinyl fluoride); PTFE; polyarylethyl ketone PAEK; and mixtures thereof.

[0091] If a ceramic is chosen as the material of construction for a component, then the ceramic is preferably selected from the group consisting of alumina, zirconia and mixtures thereof. It is preferred to select an alumina-zirconia ceramic, such as that sold by CeramTec of Plochingen, Germany under the trade mark BIOLOX *delta*. Depending on the material chosen, a smooth surface coating may be provided thereon to improve performance and reduce particulate wear debris.

[0092] The present inventors believe that metal-ceramic interfaces will provide the best resistance to wear.

Accordingly, in particularly preferred embodiments, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a first vertebral body, and
- ii) an inner surface comprising a first articulation surface comprising a non-ceramic material

b) a core member comprising:

- i) a first articulation surface comprising a ceramic, and

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface.

[0093] More preferably, the second articulation interface will also have a corresponding ceramic-metal interface.

[0094] In some preferred embodiments, the entire core member consists essentially of a ceramic, preferably a sintered polycrystalline ceramic. Preferably, the sintered polycrystalline ceramic comprises at least 50 wt% of a material selected from the group consisting of alumina, zirconia, and alumina-zirconia mixtures. In some alumina-zirconia mixture embodiments, the ceramic comprises 10-30 wt% alumina.

[0095] In some alumina-zirconia mixture embodiments, the ceramic comprises 70-90 wt% alumina. In some embodiments, the ceramic comprises alumina having a median grain size of no more than 5 μm , preferably less than 3 μm , more preferably less than 2 μm , more preferably less than 1 μm . In some embodiments, the ceramic comprises tetragonal zirconia having a median grain size of no more than 2 μm , more preferably less than 1 μm . In some embodiments, the ceramic comprises alumina made from a seeded gel process.

[0096] In some embodiments, the core member is polyethylene.

[0097] In some preferred embodiments, the first endplate consists essentially of a metallic material, preferably a titanium alloy or a chrome-cobalt alloy. In some preferred embodiments, the second endplate consists essentially of the same metallic material as the first plate.

[0098] In some embodiments, the articulation surfaces of the endplates may be coated with a wear-resistant coating, such as diamond film, in order to reduce wear.

[0099] In some embodiments, the endplates are made of a stainless steel alloy, preferably that which is available from Carpenter Specialty Alloys, Carpenter Technology Corporation of Wyomissing, PA under the trade mark BioDur CCM Plus, and the core member is made of polyethylene such as that which is available from DePuy Orthopaedics of Warsaw, IN under the trade

mark Marathon. In some embodiments, the endplate articulation surfaces are coated with a sintered bead coating such as that which is available from DePuy Orthopaedics of Warsaw, IN under the trade mark Porocoat.

[0100] In some embodiments, the endplates are made from a composite comprising carbon fibre. Composites comprising carbon fibre are advantageous in that they typically have a strength and stiffness that is superior to neat polymer materials such as a polyarylethyl ketone PAEK.

[0101] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body, and
- ii) an inner surface comprising a first articulation surface comprising a composite comprising carbon fibre, and

b) a core member comprising:

- i) a first articulation surface comprising a metal,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface.

[0102] Also in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body,
- ii) an inner surface comprising a first articulation surface, and
- iii) a body portion therebetween comprising carbon fibre, and

b) a core member comprising a first articulation surface,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface.

[0103] Preferably, the composite comprising carbon fibre further comprises a polymer. Preferably, the polymer is a polyarylethyl ketone PAEK. More preferably, the PAEK is selected from the group consisting of polyetherether ketone PEEK, polyether ketone ketone PEKK and polyether ketone PEK. In preferred embodiments, the PAEK is PEEK.

[0104] In some embodiments, the carbon fibre comprises between 1 vol% and 60 vol% (more preferably, between 10 vol% and 50 vol%) of the composite. In

some embodiments, the polymer and carbon fibres are homogeneously mixed. In others, the material is a laminate. In some embodiments, the carbon fibre is present as chopped state. Preferably, the chopped carbon fibres have a median length of between 1 mm and 12 mm, more preferably between 4.5 mm and 7.5 mm. In some embodiments, the carbon fibre is present as continuous strands.

[0105] In especially preferred embodiments, the composite comprises:

- (a) 40-99% (more preferably, 60-80 vol%) polyarylethyl ketone PAEK, and
- (b) 1-60% (more preferably, 20-40 vol%) carbon fibre,

wherein the polyarylethyl ketone PAEK is selected from the group consisting of polyetherether ketone PEEK, polyether ketone ketone PEKK and polyether ketone PEK.

[0106] In some embodiments, the composite consists essentially of PAEK and carbon fibre. More preferably, the composite comprises 60-80 wt% PAEK and 20-40 wt% carbon fibre. Still more preferably the composite comprises 65-75 wt% PAEK and 25-35 wt% carbon fibre.

[0107] If both the core and endplates are made of materials having a significantly high stiffness, then the device may not fully mimic the shock absorbing function of the natural intervertebral disc.

[0108] Therefore, in order to augment the shock absorbing function of the core member, in some embodiments, the core member comprises a shock-absorbing component characterized by a specified range of a spring constant.

[0109] Therefore, in accordance with the present invention, there is provided intervertebral motion disc comprising:

- a) a first prosthetic vertebral endplate comprising:
 - i) an outer surface adapted to be attached to a first vertebral body, and
 - ii) an inner surface comprising a first articulation surface, and
- b) a core member comprising a stiff component and a shock absorbing component having a spring constant of between 500 N/mm and 1000 N/mm, and comprising a first articulation surface,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface.

[0110] In some embodiments, the core member comprises a stiff component and a shock-absorbing component, and the shock-absorbing component has a spring constant of between about 500 N.mm⁻¹ and 1000 N.

mm⁻¹ and a thickness of between 1 mm and 5 mm. When the shock-absorbing component is so designed, it can absorb between about 1000 N and 2000 N of load.

[0111] In some embodiments, the shock absorbing function of the core is provided by a spring within the core member. Therefore, in accordance with the present invention, there is provided a core member for articulation between first and second prosthetic vertebral endplates, comprising:

- i) a first portion having a first articulation surface adapted for articulation with a first articulation surface of the first prosthetic vertebral endplate,
- ii) a second portion having a second articulation surface adapted for articulation with a first articulation surface of the second prosthetic vertebral endplate, and
- iii) a spring portion disposed between the first and second portions.

[0112] Now referring to FIG. 13, in some embodiments, the spring may be provided by simply manufacturing upper and lower halves of a core member, and then attaching the opposite ends of a compression spring to the opposite ends of the core halves. For example, in FIG. 18, upper core half 721 comprises a first articulation surface 723 and a lower attachment surface 725, while lower core half 731 comprises a second articulation surface 733 and an upper attachment surface 735. Compression spring 741 comprises upper end 743 and lower end 745, wherein the upper end 743 is attached to the lower attachment surface 725 of the upper core half, and the lower end 745 is attached to the upper attachment surface 735 of the lower core half.

[0113] Now referring to FIG. 14, in other embodiments, the spring action is provided by first providing an integral core member having opposing articulation surfaces 751, 753 and then shaping the surface of the intermediate portion of the core member with a cutting tool to provide at least one recess 755 therein that provides the spring effect. In some embodiments, the intermediate surface comprises multiple recesses spaced to provide the spring effect. In other embodiments, a helical recess is provided, as in FIG. 14. In other embodiments, the helical recess is made by using a wire and a spinning fixture to produce a deep helical slit in the core member.

[0114] Now referring to FIG. 15, the locking tab 71 is adapted to securely lock in the channel after the core member has been inserted and to retain the core member within the channel. In one preferred embodiment, the locking tab comprises a body portion 82 having deformable arms 78 extending therefrom and oriented substantially parallel to each other to fit within the channel of the superior endplate. Each arm 78 further comprises a laterally extending wing 79. Because the wing-span defined by the wings is greater than the width of the channel, the arms are deflected inwards as the tab is slid into the retaining channel. These wings are further

designed to fit within sockets 32 (of FIG. 3) laterally disposed within the channel so that the deflected arms can move back to their original parallel orientation when the wings are accepted by the channel sockets, thereby locking tab securely in place.

[0115] The locking tab should be manufactured from a material with the requisite elasticity such as stainless steel, plastic, or a shape memory alloy such as that known as Nitinol. However, in some embodiments, the elasticity of the locking tab may be relatively low, thereby making it difficult to provide the snap-in function. Accordingly, in some embodiments, the locking means is fastened to the prosthetic vertebral endplate by a fastener such as a screw or anchor.

[0116] In preferred embodiments, the locking tab is sized so as to allow the core member to move in the A-P direction. However, in other embodiments, the locking tab may be sized so as to substantially prevent any A-P movement of the core member.

[0117] Now referring to FIG. 16, in some embodiments, the locking tab further comprises an attachment portion 1001 extending from the body of the tab and adapted to attach to a patient's vertebral body. The attachment portion provides an opportunity for short term fixation of the motion disc within the disc space.

[0118] In other embodiments, the means for limiting translation comprises:

- a) a pin and slot arrangement (preferably spring loaded) wherein the slot runs in the direction of the channel,
- b) a sliding door disposed near the first opening, and
- c) a hinged door disposed near the first opening.

[0119] In some embodiments, the means for limiting translation comprises a third component shaped to be inserted into the channel from the direction of the inner surface of the endplate.

[0120] Now referring to FIG. 15, in some embodiments, the tab is provided with an inner surface 81 adapted to mate with the outer surface of the core member. In preferred embodiments, the inner surface of the tab is concave and substantially hemispherical.

[0121] In some embodiments, the inner surface of the tab can be further shaped so as to provide substantial translational motion. Now referring to FIG. 17, the tab 601 comprises an inner surface having an elongated portion 603 and a hemispherical portion 605, wherein the elongated portion allows for substantial translation of the core 607 therein. In this case, the channel 609 formed within the inner surface of the endplate 611 can be relatively short. In other embodiments, the channel formed within the inner surface of the endplate can be simply a back wall. The tab of this embodiment can be affixed to the endplate by any conventional means.

[0122] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc

comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body, and
- ii) an inner surface comprising:

- a first articulation surface, and
- a raised portion extending from the inner surface substantially adjacent the first articulation surface and having first and second ends, and

b) a removable tab having first and second ends,

wherein the tab is attached to the endplate and oriented so that the first end of the raised portion is substantially adjacent the first end of the tab, and the second end of the raised portion is substantially adjacent the second end of the tab to form an enclosure which substantially encloses the first articulation surface.

[0123] Now referring to FIG. 18, in some embodiments, the translation surface of the retaining channel is disposed below the level of peripheral surface 115 of the prosthetic vertebral endplate. In this case, the interior portion of the outer surface of the endplate forms a keel to promote the initial and long-term stability of the device, and the translation surface 123 of the retaining channel is contained within the keel. In addition, this embodiment allows the translation surface of the core member to contact the translation surface 123 of the endplate at a much lower location. Therefore, either the overall height of the device could be reduced (thereby allowing for easier insertion of the core member) or the height of the core member could be increased (to provide increased strength). In addition, the large surface area of the keel could be porous coated to promote bony ingrowth.

[0124] Therefore, in accordance with the present invention, there is provided a prosthetic vertebral endplate 111 comprising:

- i) an outer surface 113 having a peripheral portion 115 and an interior portion 117, each portion being adapted to be attached to a vertebral body, and
- ii) an inner surface 119 comprising an opening 120 forming a channel 121 defining a channel depth DE_{CH} ,

wherein the peripheral portions of the inner and outer surfaces define a peripheral depth DE_p , and

wherein the channel depth is at least 80% of (and preferably is at least as great as) the peripheral depth.

[0125] Also in accordance with the present invention, there is provided prosthetic vertebral endplate comprising:

i) an outer surface having:

- a) a peripheral portion adapted to mate with a vertebral body, and
- b) an interior portion forming a keel having a width,

ii) an inner surface comprising an opening forming a channel having a width,

wherein the keel width is greater than the channel width.

[0126] In this condition, the keel is wide enough to accommodate at least a portion of the channel and therefore at least a portion of the core member. When the keel can accommodate the core member, the overall height of the device may be advantageously decreased.

[0127] Whereas the embodiments of the present invention disclosed thus far each possess an open-ended channel having a pair of side walls for limiting the medial-lateral translation motion of the core member, other embodiments of the present invention possess other means for limiting the medial-lateral translation motion of the core member while allowing easy A-P insertion of the core member.

[0128] Now referring to FIG. 19, there is provided an endplate 1201 having an inner surface 1203 and a projection 1205 extending therefrom. The projection runs from the anterior wall 1207 to the posterior wall 1209 of the endplate. Core member 1211 has a recess 1213 having a shape that mates with the projection 1205. Sidewalls 1215 and 1217 of the projection limit the lateral translation of the core member. The articulation surface of the endplate may be either the inner surface 1203 or the upper surface 1217 of the projection.

[0129] Expulsion of the core member of this embodiment can be prevented by any number of means. For example, after the core member is slid upon the projection locking clips can be put in place at either end of the projection. Alternatively, the upper surface of the projection can comprise at least one flexible tab that allows passage of the recess of the core member towards the inner portion of the endplate, but prevents its passage back out.

[0130] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body, and
- ii) an inner surface comprising a first articulation surface, and
- iii) an elongated rail extending from the inner surface,

b) a core member comprising:

- i) a first articulation surface, and
- ii) an elongated slot for receiving the rail,

wherein the first articulation surface of the core member and the first articulation surface of the first endplate are adapted to form a first articulation interface, and

the elongated rail is received in the elongated slot.

[0131] Although the primary function of the guide rails on the superior and inferior prosthetic endplates is to mate with instrumentation during the surgical procedure, they are also designed to accommodate the addition of optional device components. For example, if the surgeon sought to render the device completely immobile for the first few weeks immediately following implantation, the surgeon could add a stabilizing component to the device. For example, one possible geometry for such a stabilization component would be a "U" shape that could be slid into place along the guide rails. In the preferred embodiment, the stabilization component could be made of a bioresorbable material that would provide support for a few weeks after implantation and then resorb and allow the device to restore motion to the spinal segment.

[0132] In other embodiments, the additional stabilization component can transform the motion disc into a permanent spacer that prevents motion. In this case, the component would likely be used by a surgeon in a revision case. If the patient continued to experience pain or other problems after the implantation of the artificial disc replacement device, then the surgeon may feel that it would be best to reoperate and substantially eliminate motion from the spinal segment. Since the removal of implants is often problematic, the stabilization component would provide a much-desired alternative. Rather than removing the artificial disc replacement device, the surgeon could simply slide the stabilization member into place and essentially convert the motion disc into a spacer.

[0133] Therefore, in accordance with the present invention, there is provided intervertebral spacer, comprising:

a) a first motion segment comprising:

- i) an outer surface adapted to mate with a first vertebral body,
- ii) an inner surface comprising a motion surface, and
- iii) a body portion therebetween having an anterior portion and a posterior portion,

and

b) a second motion segment comprising:

- i) an outer surface adapted to mate with a second vertebral body,
- ii) an inner surface comprising a motion sur-

face, and

iii) a body portion therebetween having an anterior portion and a posterior portion, and

c) a spacing component having a first surface and an opposing second surface,

wherein the motion surfaces are adapted to form a motion interface, and

wherein the spacing component is disposed between the inner surfaces of the motion segments to substantially prevent motion at the motion interface.

[0134] In some embodiments, the spacing component is substantially U-shaped. Preferably, the substantially U-shaped spacing component has first and second end portions disposed substantially parallel to each other. In some embodiments, the first end of the spacing component is oriented substantially in the anterior-posterior direction, while in others, the first end of the spacing component is oriented at a substantial angle from the anterior-posterior direction. Preferably, this spacing component is adapted to be inserted from the anterior direction.

[0135] In some embodiments adapted to be inserted from the posterior direction, the spacing component comprises first and second independent bodies.

[0136] In some embodiments, the spacing component comprises a biologic enhancement selected from the group consisting of osteoinductive materials, osteoconductive materials, and osteogenic materials.

[0137] In some embodiments, the spacing component comprises stem cells.

[0138] The present invention is designed such that the implantation of the device can be accomplished in a straightforward manner with a minimum of distraction. The guides are designed such that the superior and inferior prosthetic vertebral endplates can be placed on an instrument that will hold them very close together without allowing the articulation surfaces to touch. The prosthetic vertebral endplates can then be inserted into the disc space in this position. This allows the surgeon to insert these components without having to significantly overdistraction the disc space. The instrument can then separate the prosthetic vertebral endplates and securely force them against their respective natural vertebral endplates. At this point, a sizing tool can be used to determine the ideal height of the disc space and the appropriately sized core member can be selected. The core member is then slid into place within the retaining channel and the instrument is removed. The surgeon can then perform a final check of the placement and sizing of the device. If the surgeon is satisfied, the locking tab is secured in place.

[0139] In preferred embodiments, the disc can be inserted modularly into the disc space, wherein the endplates are first inserted (either at the same time or consecutively) and then the core member is inserted. Because the distance separating the endplates at the pe-

riphery of the disc exceeds the height of a concave core member, the core member may be inserted between the prosthetic endplates without excessive overdistraction of the disc space.

[0140] Therefore, in accordance with the present invention, there is provided a intervertebral motion disc comprising:

a) a first prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a first vertebral body,
- ii) an inner surface comprising an inner portion and a peripheral portion,

wherein at least one of the portions comprises a first articulation surface, and

b) a second prosthetic vertebral endplate comprising:

- i) an outer surface adapted to be attached to a second vertebral body,
- ii) an inner surface comprising an inner portion and a peripheral portion,

wherein at least one of the portions comprises a first articulation surface,

c) a core member comprising:

- i) a first articulation surface adapted for articulation with the first articulation surface of the first endplate, and
- ii) a second articulation surface adapted for articulation with the first articulation surface of the second endplate, and

d) means for limiting the translation motion of the core member,

wherein the core member is disposed between the endplates and oriented therein to produce a first articulation interface between the first articulation surface of the first endplate and the first articulation surface of the core member, and a second articulation interface between the first articulation surface of the second endplate and the second articulation surface of the core member, and a distance between the peripheral portions of the first and second endplates, and

wherein the distance between the peripheral portions is greater than the height of the core member.

[0141] Because the motion disc of the present invention will substantially mimic the motion of the natural intervertebral disc, there may be times in which the spine hyperextends to create an extreme lordotic posture. In these situations, the distance between the anterior portions of the prosthetic vertebral endplates may become unacceptably large. In order to limit the extent of lordotic hyperextension, in some embodiments, a ligament is at-

tached between the anterior portions of the endplates.

[0142] Therefore, in accordance with the present invention, there is provided an intervertebral motion disc comprising:

a) a first motion segment comprising:

- i) an outer surface adapted to mate with a first vertebral body,
- ii) an inner surface comprising a motion surface, and
- iii) a body portion therebetween having an anterior portion and a posterior portion,

b) a second motion segment comprising:

- i) an outer surface adapted to mate with a second vertebral body,
- ii) an inner surface comprising a motion surface, and
- iii) a body portion therebetween having an anterior portion and a posterior portion, and

c) a ligament having a first end and a second end,

wherein the motion surfaces are adapted to form a motion interface, and

wherein the first end of the ligament is connected to the anterior portion of the first motion segment and the second end of the ligament is connected to the anterior portion of the second motion segment.

[0143] Preferably, the ligament comprises a biocompatible flexible material. More preferably, the biocompatible flexible material is selected from the group consisting of:

- i) a polyester fibre weave,
- ii) an elastic material (such as silicon, polyurethane, and natural rubber),
- iii) a polyvinyl material, and
- iv) a biological material capable of forming a scaffold for natural regeneration of a resected ligament, such as small intestinal submucosa SIS.

[0144] Any of the devices disclosed in the FIGS. may be rotated through 180° so that the inferior and superior endplates swap places. In addition, the articulation surfaces of the core member could be made either concave or convex. For example, FIG. 20 provides one such alternative embodiment wherein the core member has a convex articulation surface. Moreover, additional components could be added to the device to enhance the design such as screws through the endplates to provide for improved fixation as shown in FIG. 25.

[0145] Now referring to FIGS. 21a and 21b, there is provided an alternative embodiment of the present invention. The intervertebral motion disc of FIG. 21 is substantially similar to the motion disc of FIG. 1, with the fol-

lowing modifications:

First, the relative size of the core member in FIGS. 21a and 21b is substantially larger than that of the core member in FIG. 1 and is preferably made of a polymeric material such as polyethylene.

Second, the second articulation interface formed by the core member and the upper endplate is slightly curved and hemicylindrical. The slight curve of the hemicylinder is oriented in the A-P direction (as shown in FIG. 21b), while the linear dimension thereof is oriented in the M-L direction (as shown in FIG. 21a). The articulation interfaces are oriented in the same direction.

[0146] Now referring to FIGS. 22a and 22b, there is provided a motion disc substantially similar to that shown in FIGS. 21a and 21b, except that the slight curve of the hemicylinder is oriented in the M-L direction (as shown in FIG. 22a), while the linear dimension thereof is oriented in the A-P direction (as shown in FIG. 22b).

[0147] Now referring to FIG. 23, there is provided an endplate for a motion disc wherein the sidewall of the endplate comprises a third opening 301 in communication with the first opening in the sidewall and the second opening in the inner surface, so that the channel formed thereby is substantially open at each of its ends. A small lip 305 rises from the bottom surface of the posterior end of the channel and functions to keep the core from sliding out the posterior end of the channel.

[0148] Now referring to FIG. 24, there is provided another embodiment of the present invention in which the means comprises a locking tab comprising first and second arms, the endplate further comprises first and second lateral wall portions comprising first and second respective recesses, wherein the first arm is shaped to be secured to the endplate in the first recess, and the second arm is shaped to be secured to the endplate in the second recess. In this FIG., the tab is secured in place.

[0149] Now referring to FIG. 25, there is provided another embodiment of the present invention in which one endplate is adapted to receive a screw for fixation to an adjacent vertebra. In this FIG., the screw is received within the through-hole.

Claims

1. A prosthetic vertebral endplate comprising:

- i) an outer surface adapted to mate with a vertebral body,
- ii) an inner surface having a first opening thereon,
- iii) a body portion connecting the inner and outer surfaces and defining a sidewall comprising a second opening thereon, and
- iv) an articulation surface suitable for support-

ing articulation motion, wherein the first and second openings communicate to form a channel having a first open end.

2. An endplate as claimed in claim 1 wherein the articulation surface is disposed within the channel. 5
3. An endplate as claimed in claim 1 wherein the sidewall has an anterior portion, and the channel has a bottom surface extending smoothly to the anterior portion of the sidewall. 10
4. An endplate as claimed in claim 1 wherein the channel has a bottom surface having a lip extending therefrom towards the inner surface. 15
5. An endplate as claimed in claim 4 wherein the lip is disposed substantially near the sidewall.
6. An endplate as claimed in claim 4 wherein the lip has a height that is no more than 80% of the height of the channel. 20
7. An endplate as claimed in claim 1 wherein the articulation surface is disposed upon the inner surface. 25
8. An endplate as claimed in claim 1 wherein the sidewall further comprises a third opening thereon, wherein the first and third openings communicate to form a second open end in the channel. 30
9. An endplate as claimed in claim 1 wherein the articulation surface is substantially flat. 35
10. An endplate as claimed in claim 1 wherein the articulation surface is slightly hemicylindrical. 40

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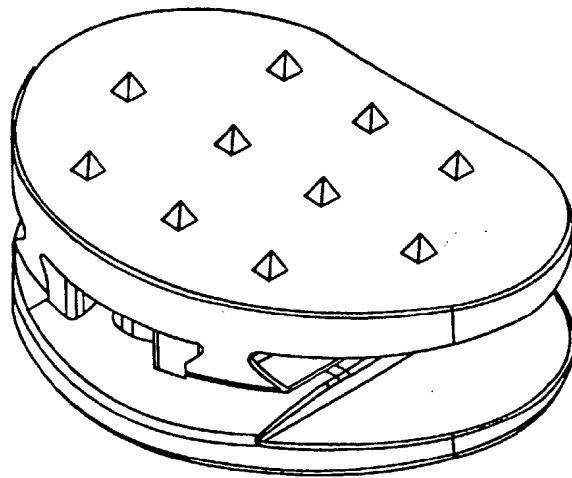


FIG. 1A

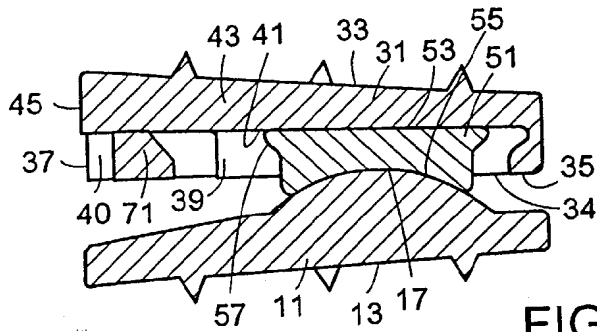


FIG. 1B

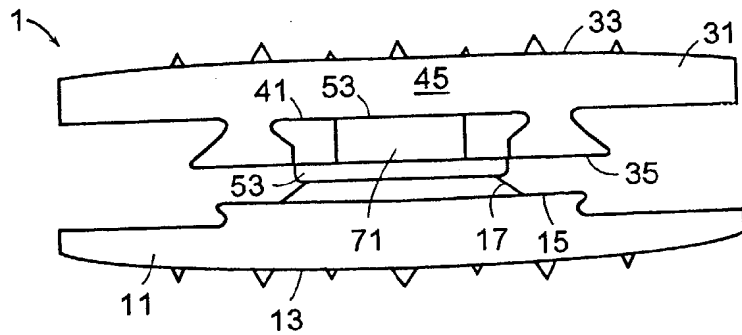
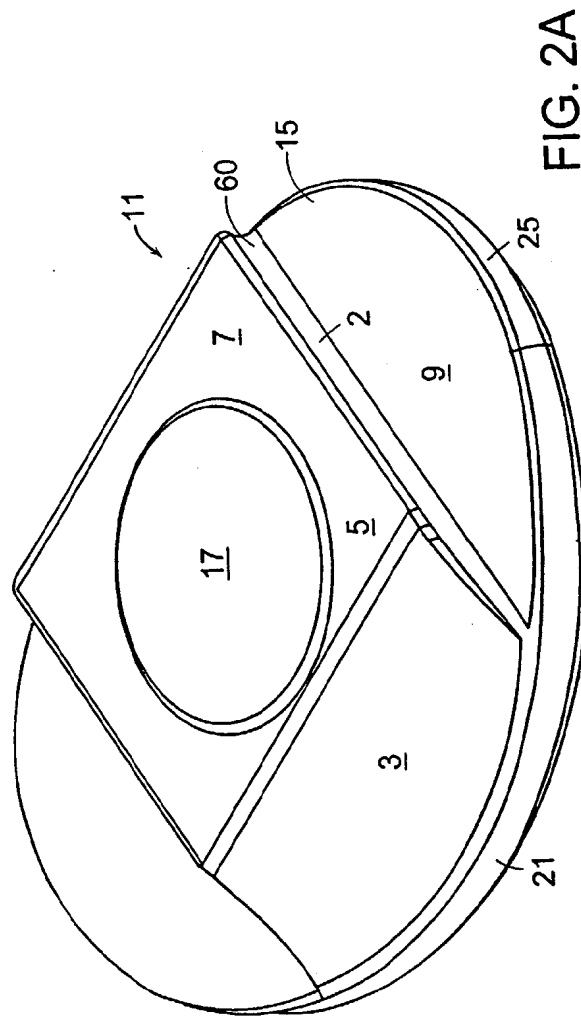
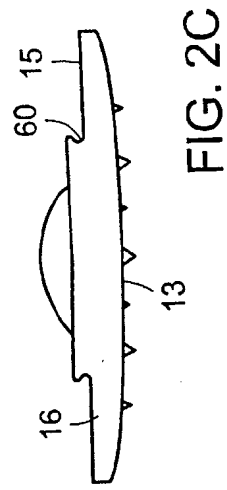
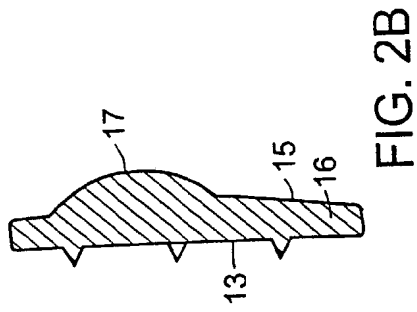
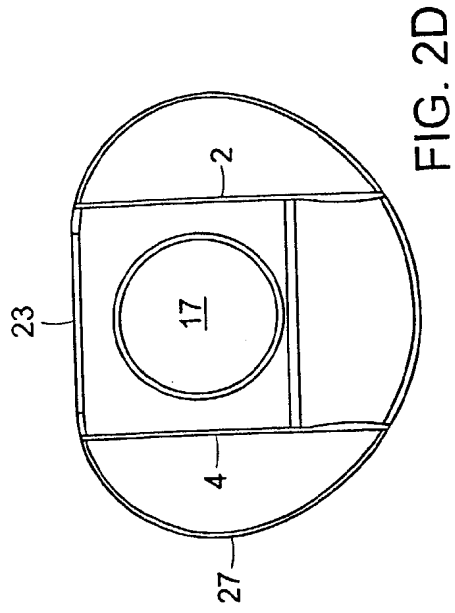


FIG. 1C



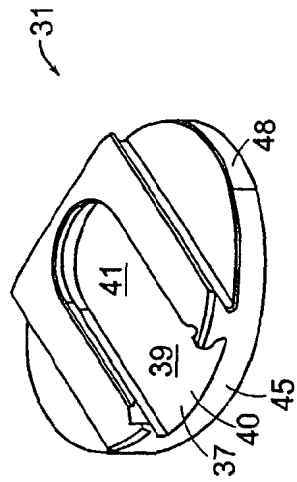


FIG. 3A

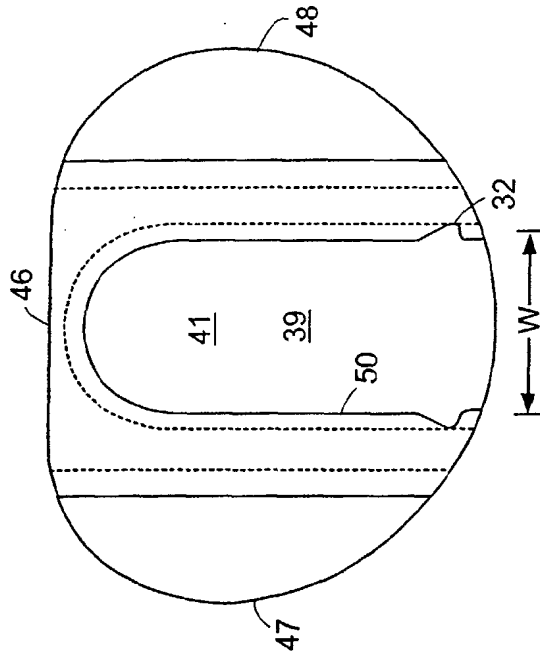


FIG. 3B

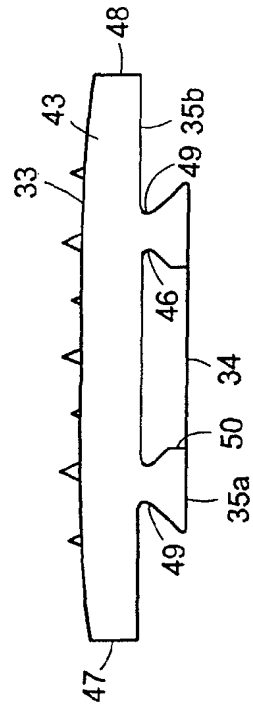


FIG. 3C

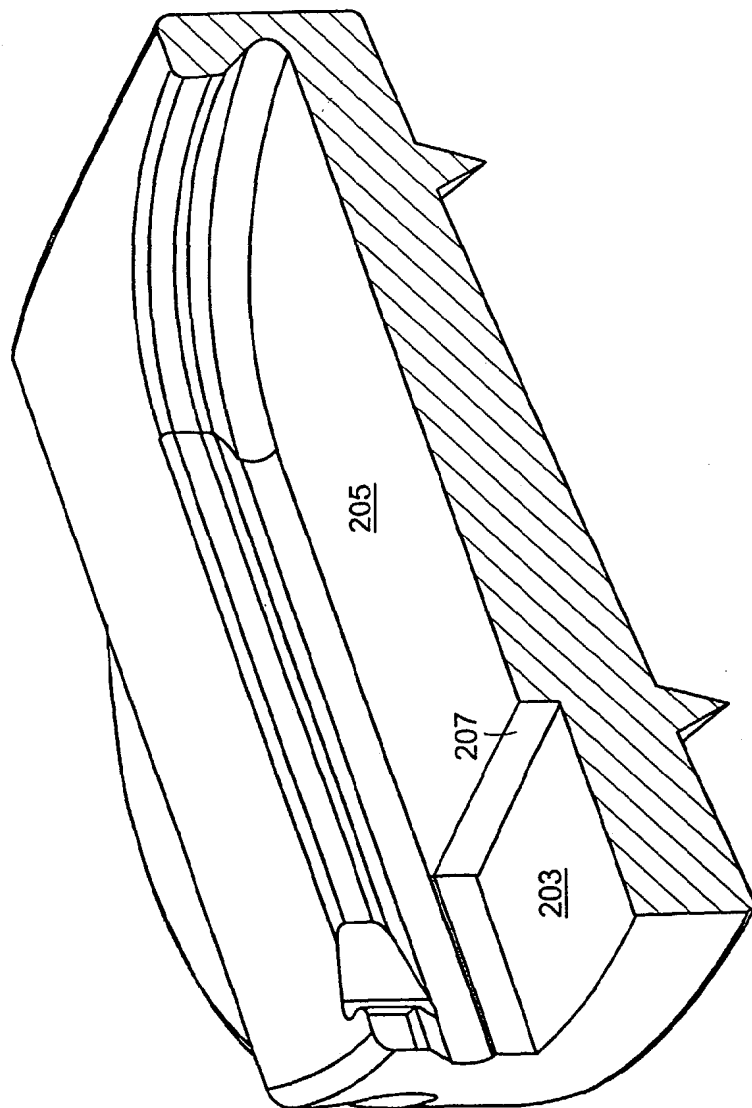


FIG. 4

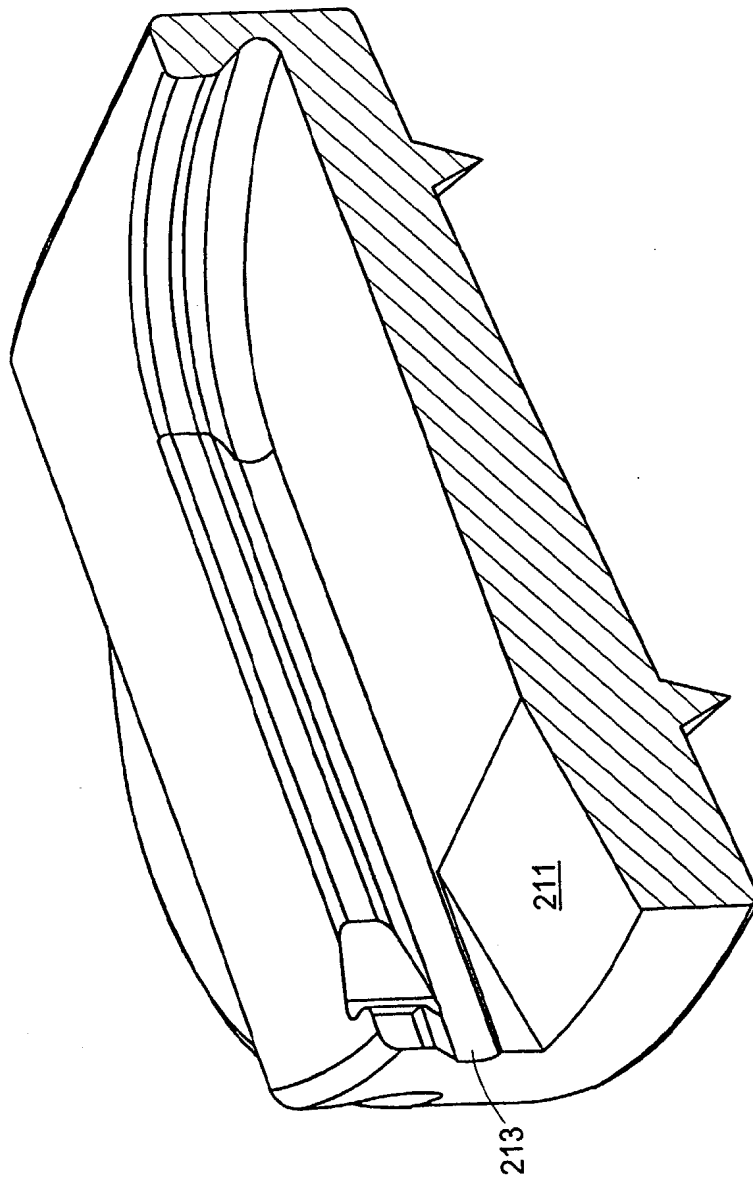


FIG. 5

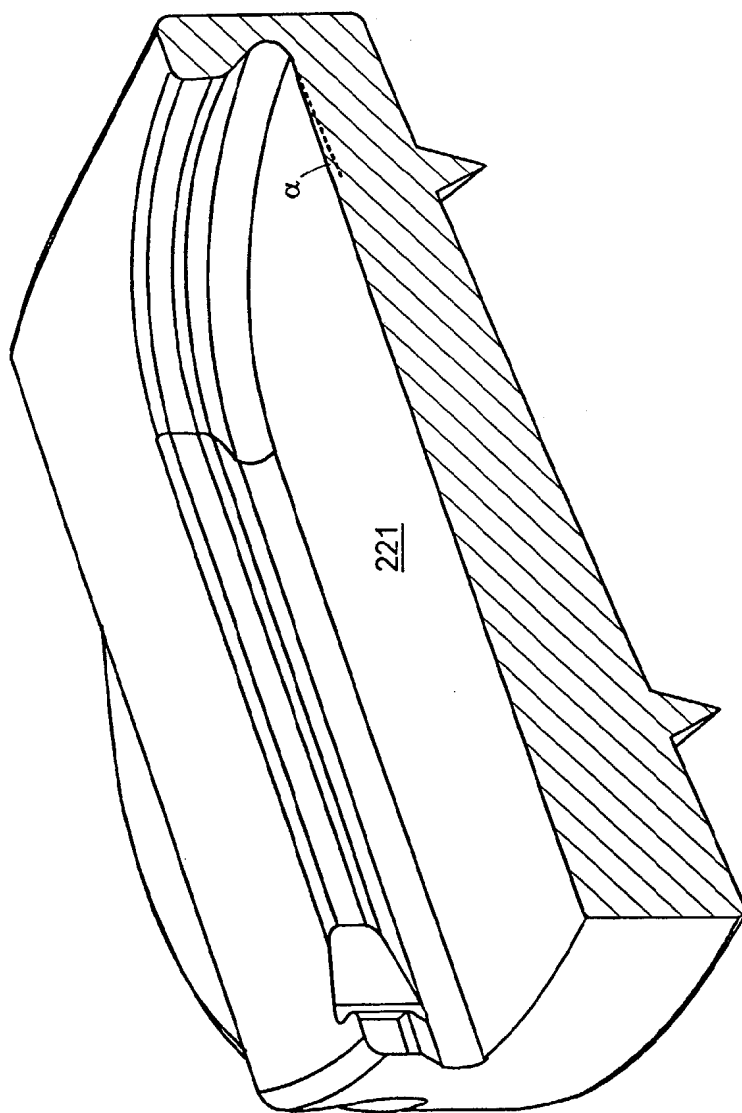


FIG. 6

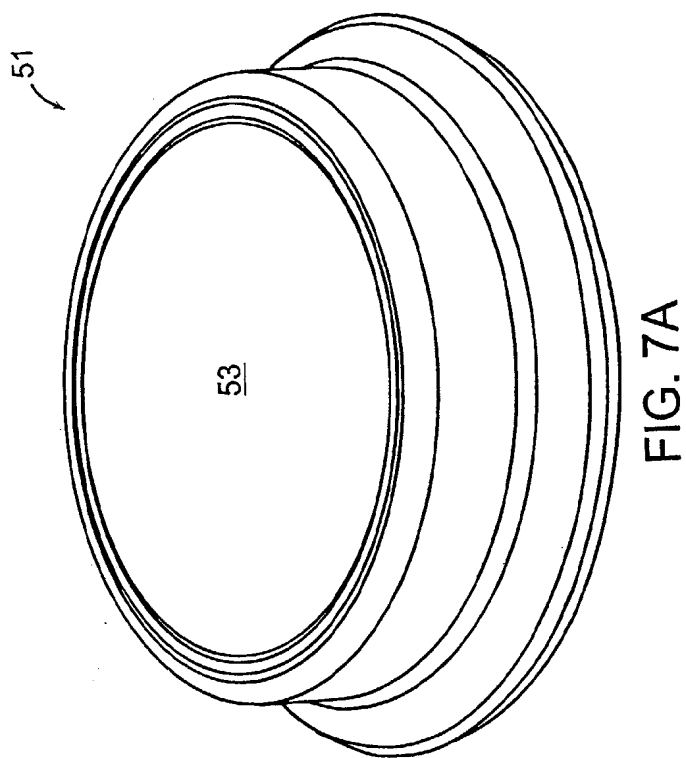


FIG. 7A

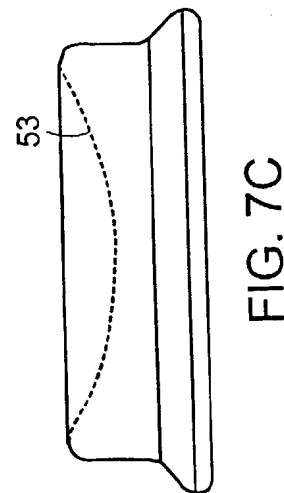


FIG. 7C

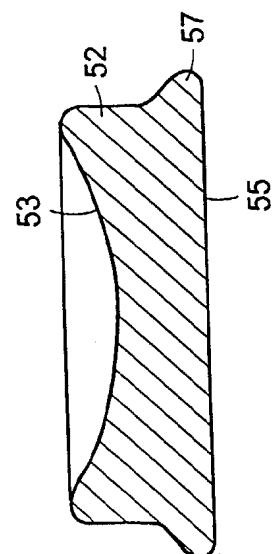


FIG. 7B

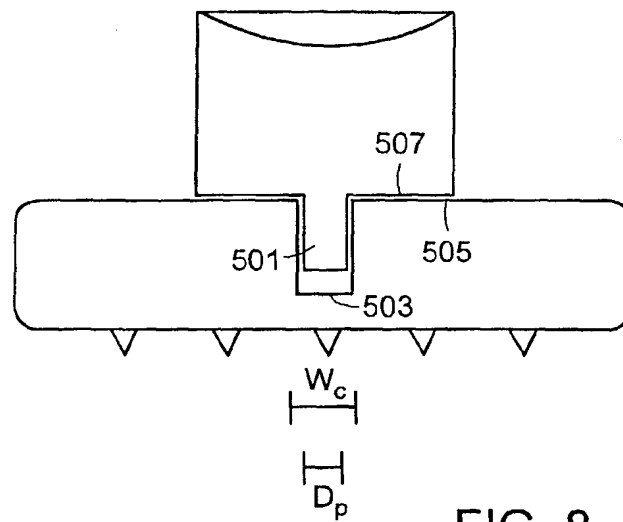


FIG. 8

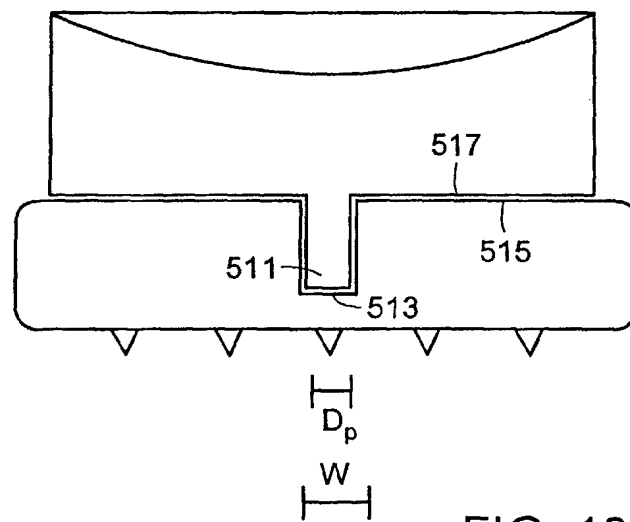


FIG. 10

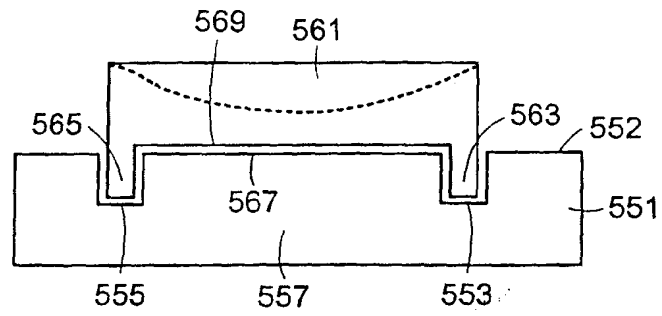


FIG. 9

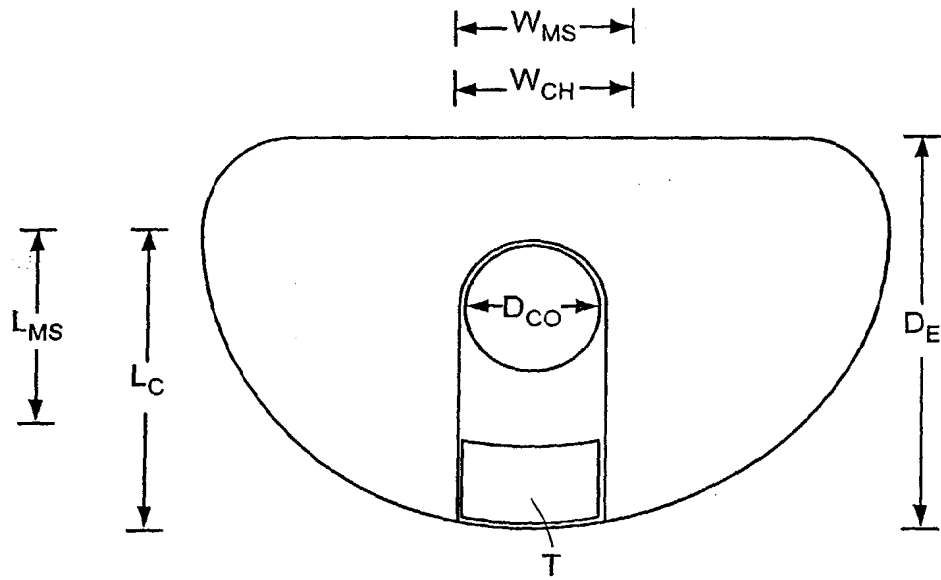


FIG. 11

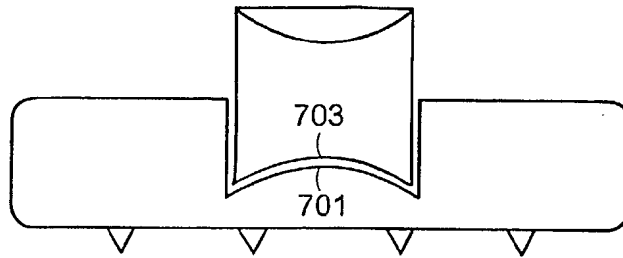


FIG. 12

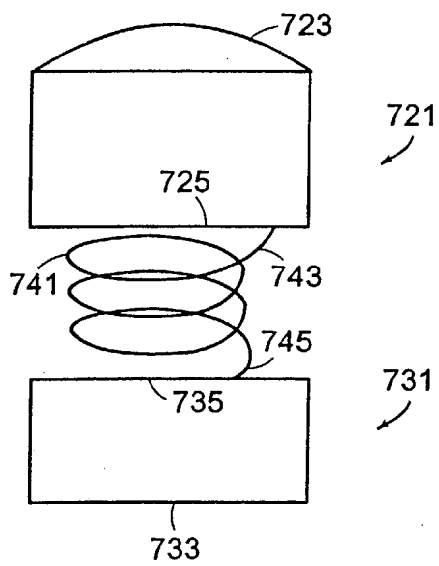


FIG. 13

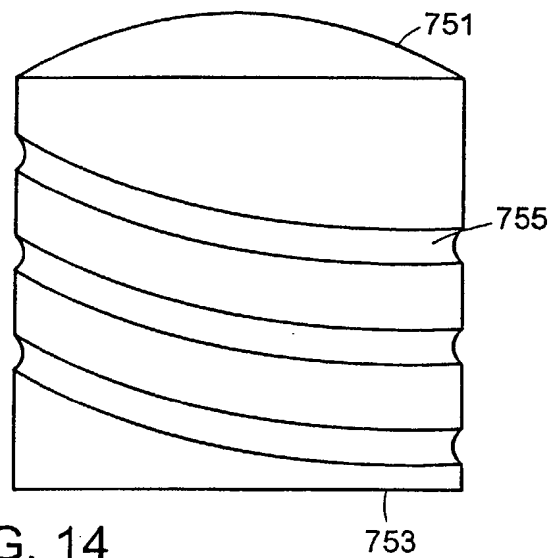


FIG. 14

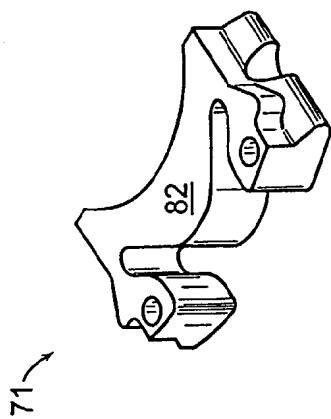


FIG. 15A

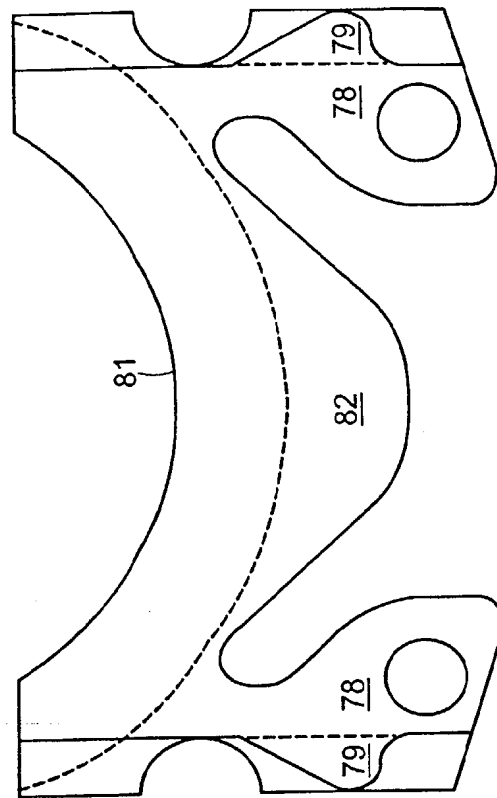


FIG. 15B

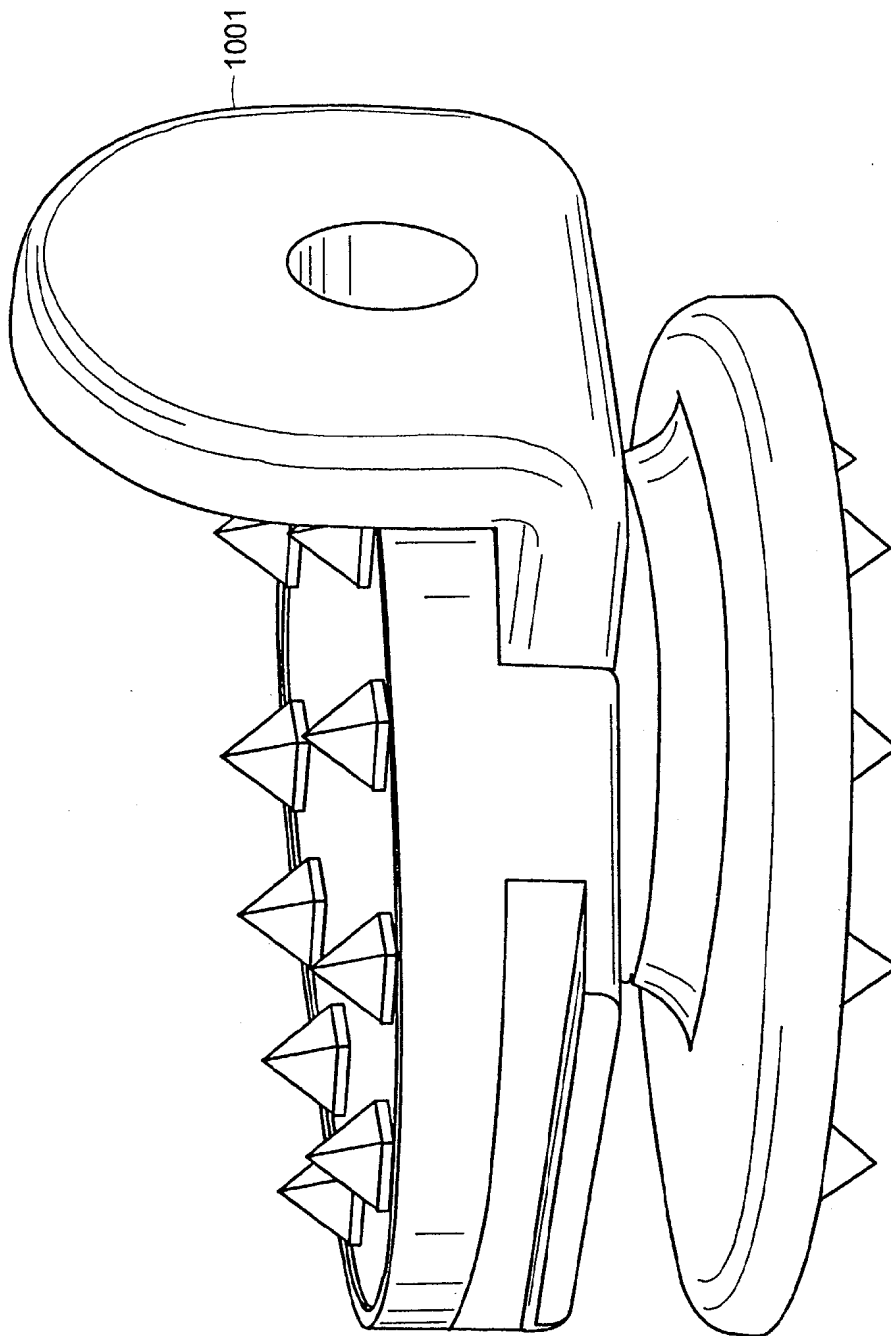


FIG. 16

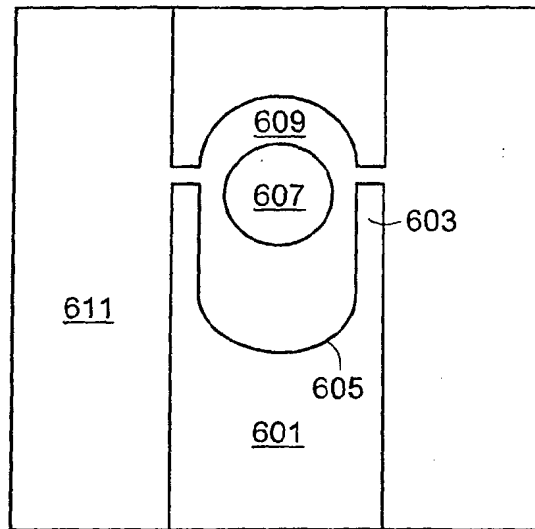


FIG. 17

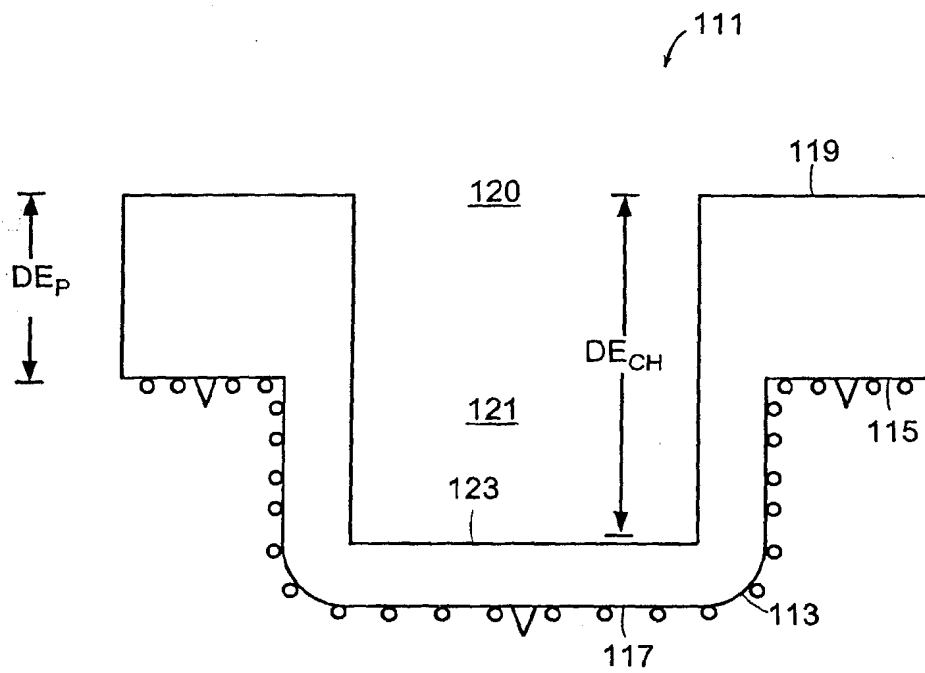
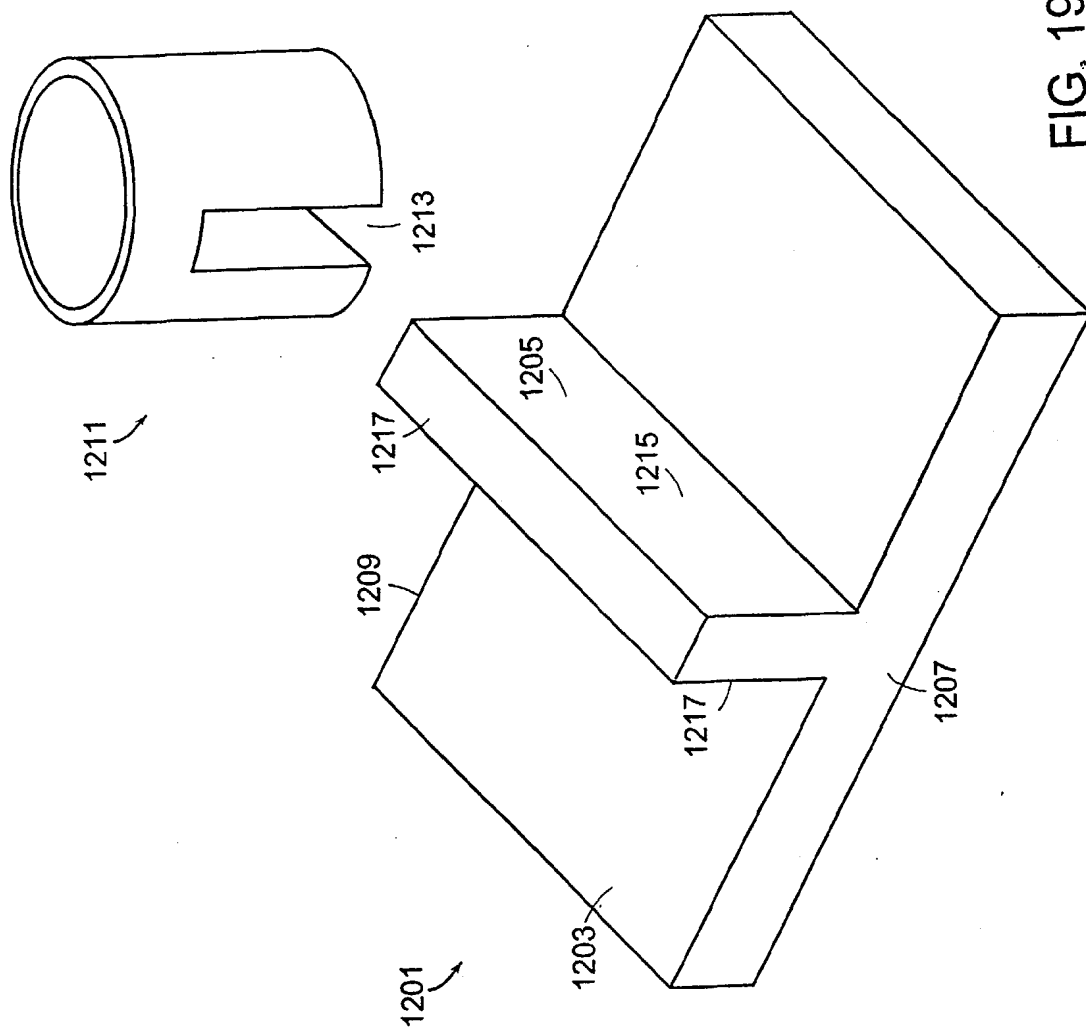


FIG. 18



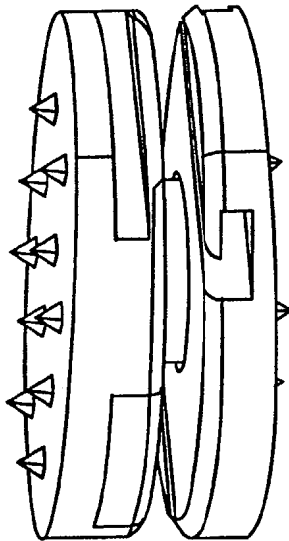


FIG. 20A

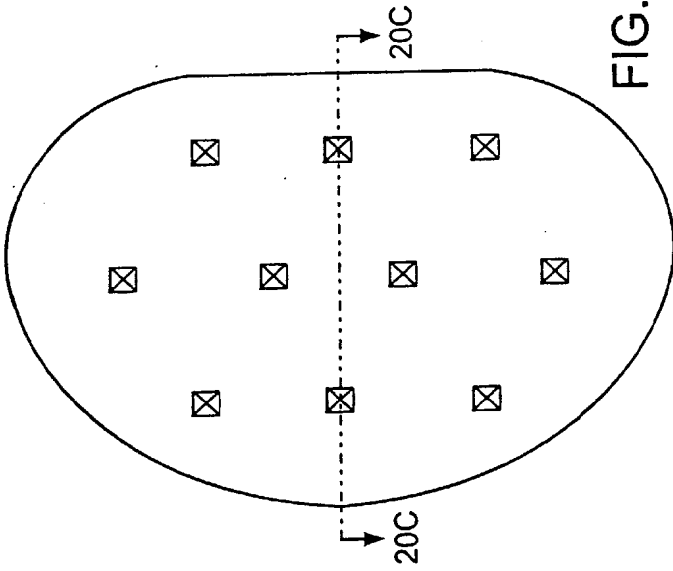


FIG. 20B

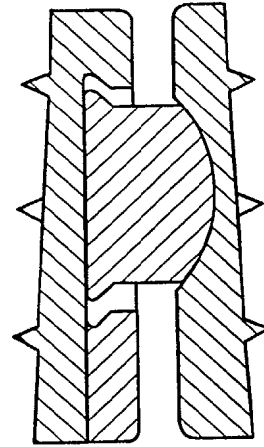


FIG. 20C

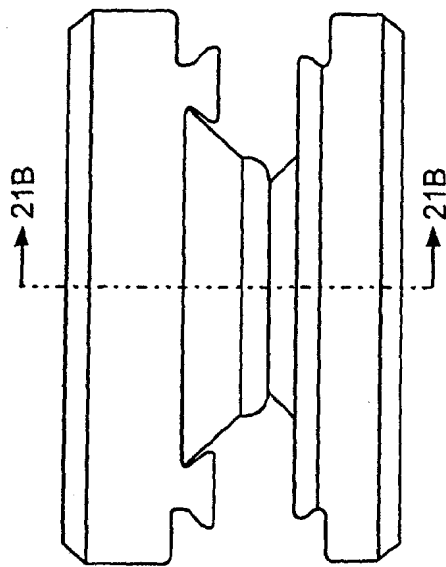


FIG. 21A

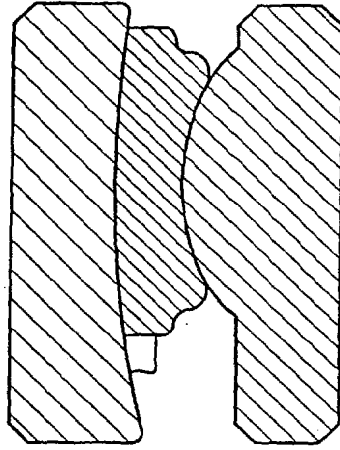


FIG. 21B

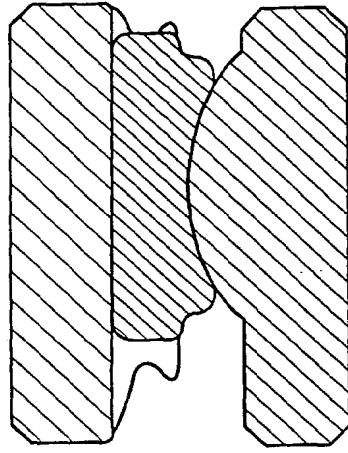


FIG. 22B

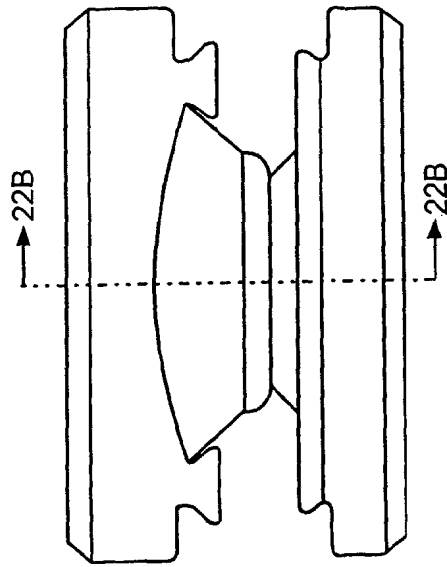


FIG. 22A

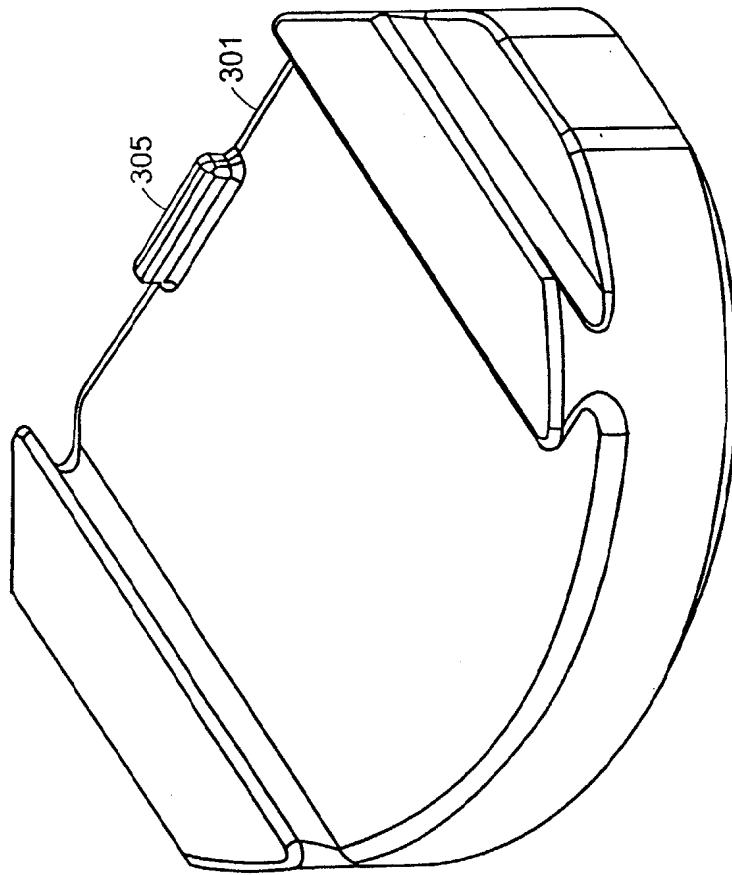


FIG. 23

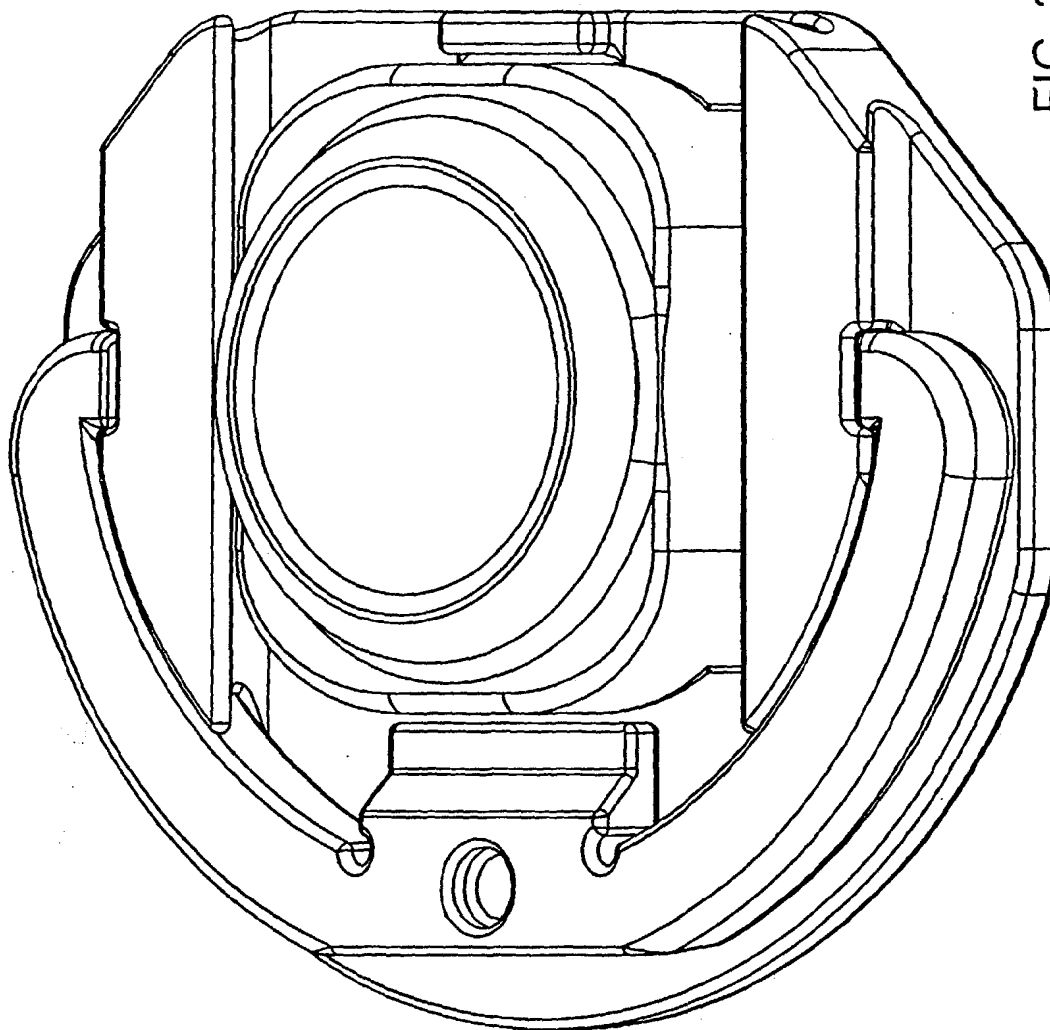


FIG. 24

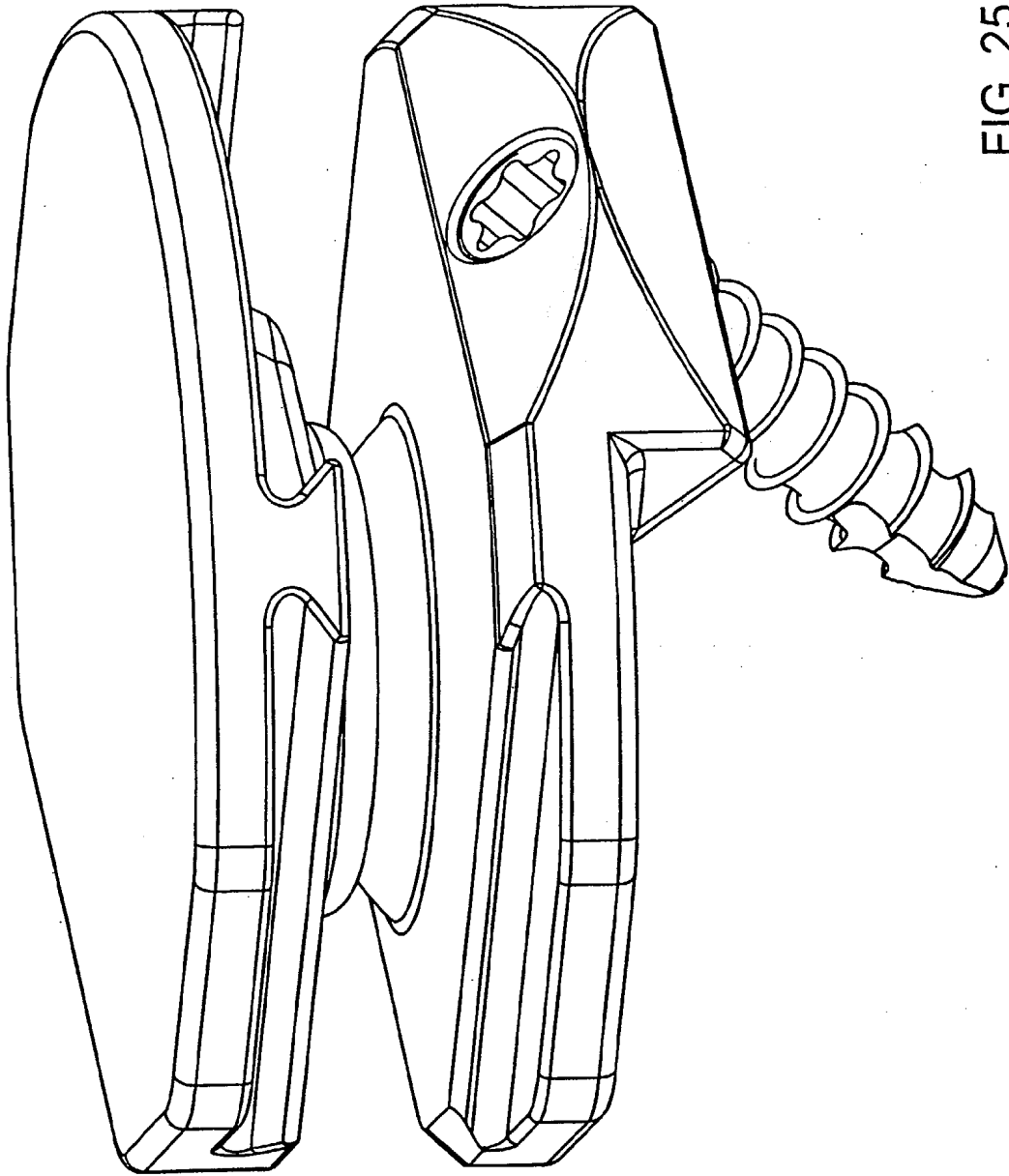


FIG. 25



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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	WO 99 53871 A (CAUTHEN RESEARCH GROUP INC) 28 October 1999 (1999-10-28) * page 7, line 20 - line 32 * * figure 10 * ---	1-3,7,8,10	A61F2/44
X	EP 0 282 161 A (HEALTH & RESEARCH SERVICES INC) 14 September 1988 (1988-09-14) * column 3, line 1 - line 10 * * figure 1 * ---	1,2,10	
X	FR 2 730 159 A (TEULE JEAN GERMAIN) 9 August 1996 (1996-08-09) * page 4, line 25 - page 6, line 2 * * page 10, line 24 - line 35 * * figures * ---	1,2,8,9	
Y	FR 2 718 635 A (AXCYL MEDICAL) 20 October 1995 (1995-10-20) * page 3, line 36 - page 5, line 7 * ---	3-6	
Y	US 6 368 350 B1 (GRIFFITH STEVEN L ET AL) 9 April 2002 (2002-04-09) * column 6, line 38 - column 9, line 12 * ---	1-3,7,9	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61F
Y	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) * page 1 * * page 9, paragraph 2 * * page 12, paragraph 2 * * figure 1 * -----	1-3,7,9	
The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 4 November 2003	Examiner Buchmann, G
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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04-11-2003

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 9953871	A	28-10-1999	US	6019792 A	01-02-2000
			AU	3758799 A	08-11-1999
			CA	2329363 A1	28-10-1999
			EP	1075236 A1	14-02-2001
			JP	2002512079 T	23-04-2002
			WO	0115638 A1	08-03-2001
			WO	9953871 A1	28-10-1999
			US	6179874 B1	30-01-2001
			US	6440168 B1	27-08-2002

EP 0282161	A	14-09-1988	CA	1283501 C	30-04-1991
			AT	79242 T	15-08-1992
			DE	3873566 D1	17-09-1992
			DE	3873566 T2	21-01-1993
			EP	0282161 A1	14-09-1988
			JP	1308557 A	13-12-1989
			JP	1862420 C	08-08-1994
			JP	5070470 B	05-10-1993
			US	4759769 A	26-07-1988

FR 2730159	A	09-08-1996	FR	2730159 A1	09-08-1996

FR 2718635	A	20-10-1995	FR	2718635 A1	20-10-1995

US 6368350	B1	09-04-2002	AU	3873000 A	28-09-2000
			WO	0053127 A1	14-09-2000

WO 0101893	A	11-01-2001	DE	29911422 U1	12-08-1999
			WO	0101893 A1	11-01-2001
			AU	7224500 A	22-01-2001
			BR	9917397 A	05-03-2002
			CA	2391330 A1	11-01-2001
			EP	1194088 A1	10-04-2002
			JP	2003503154 T	28-01-2003

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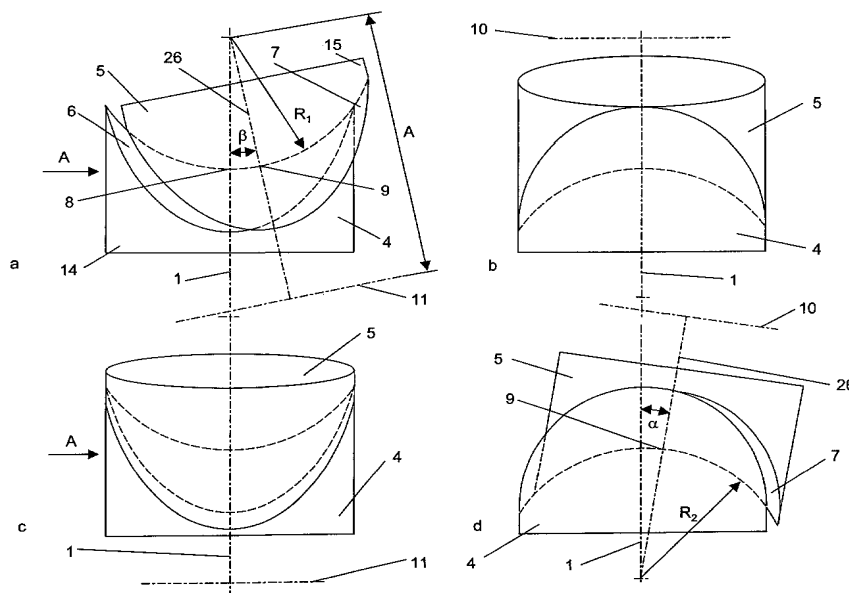
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[Fortsetzung auf der nächsten Seite]

(54) Title: IMPLANT COMPRISING A TWO-PIECE JOINT

(54) Bezeichnung: IMPLANTAT MIT ZWEIFTEILIGEM GELENK



(57) Abstract: Disclosed is an implant, particularly an intervertebral implant comprising A) two joint parts (4; 5), each of which is provided with a central axis (1; 26), a curved sliding surface (6; 7) that intersects the central axes (1; 26), and an axially outer end (14; 15) that can be connected to a bone; B) the sliding surfaces (6; 7) are embodied in a curved manner and can be displaced on top of each other; D) the second joint part (5) is rotatable relative to the first joint part (4) about two arranged rotating shafts (10; 11).

[Fortsetzung auf der nächsten Seite]

WO 2004/026186 A1

**Veröffentlicht:**

— mit internationalem Recherchenbericht

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(57) Zusammenfassung: Implantat, insbesondere Zwischenwirbelimplantat mit A) zwei Gelenkstücken (4; 5), welche je eine Zentralachse (1; 26), je eine gekrümmte, die Zentralachsen (1; 26) schneidende Gleitfläche (6; 7) und je ein axial aussenstehendes, mit einem Knochen verbindbares Ende (14; 15) aufweisen, wobei B) die Gleitflächen (6; 7) gekrümmt ausgebildet sind und aufeinander verschiebbar sind, wobei D) das zweite gelenkstück (5) um zwei windschief angeordnete Drehachsen (10; 11) relativ zum ersten Gelenkstück (4) rotierbar ist.

Implantat mit zweiteiligem Gelenk

Die Erfindung bezieht sich auf ein Implantat, insbesondere ein Zwischenwirbelimplantat gemäss dem Oberbegriff des Patentanspruchs 1.

Bei einzelnen Gelenken am menschlichen Körper, beispielsweise dem Gelenk zwischen distaler Femurkondyle und Patella, oder zwischen Metacarpalia und distaler Phalanx findet man Artikulationsflächen, welche eine bevorzugte Artikulation um eine oder mehrere Gelenkachsen zulassen und andererseits eine Artikulation um alle anderen räumlich möglichen Drehachsen einschränken oder gar nicht zulassen. Implantate mit einem mehrere Drehachsen aufweisenden Gelenk werden andererseits auch als Zwischenwirbelimplantate respektive Bandscheibenendoprothesen eingesetzt.

Eine oder mehrere beschädigte, natürliche Bandscheiben oder auch ein beschädigter Nukleus einer Bandscheibe werden üblicherweise entfernt und teilweise durch Implantate oder Prothesen ersetzt, welche in den Zwischenwirbelraum zwischen den beiden benachbarten Wirbelkörpern eingebracht werden. Dabei besteht das Ziel, wieder möglichst natürliche Zustände herbeizuführen, d.h. insbesondere die ursprüngliche Bandscheibenhöhe und damit den ursprünglichen Abstand zwischen den beiden benachbarten Wirbelkörpern wieder herzustellen. Bewegungen der Wirbelkörper sollen ohne Beeinträchtigung durch das Implantat oder die Prothese auch weiterhin in ihrem natürlichen Bereich ausführbar sein. Hierzu ist die Erhaltung der Bewegungsmöglichkeiten bei einer Vorwärts/Rückwärtsneigung, d.h. Flexion oder Extension der Wirbelsäule sowie bei einer lateralen Beugung der Wirbelkörper innerhalb der natürlichen Grenzen wesentlich. Ebenfalls soll eine räumliche Positionsänderung der benachbarten Wirbelkörper relativ zueinander innerhalb des physiologischen Bewegungsbereiches ermöglicht werden.

Eine als Ersatz für eine Bandscheibe implantierbare Vorrichtung ist aus der US 6,368,350 ERICKSON bekannt. Diese bekannte Vorrichtung umfasst im wesentlichen zwei Gelenkteile mit Endplatten. Das aus einem konvexen und einem komplementär konkaven Gelenkteil bestehende Gelenk weist in einer Ausführungsform sphärische Artikulationsflächen auf, so dass Rotationen der Gelenkteile um verschiedene in einer

Ebene liegende Drehachsen möglich sind und keine Einschränkung auf eine Drehachse für laterale Biegung der Wirbelkörper und eine weitere Drehachse für Flexion/Extension der Wirbelkörper stattfindet. Ferner ist eine Rotation der angrenzenden Wirbelkörper um deren Längsachse ohne Einschränkung möglich. In einer anderen Ausführungsform sind die Artikulationsflächen Oberflächen eines Ellipsoides, so dass die Drehachsen ebenfalls nicht auf eine Drehachse für laterale Biegung der Wirbelkörper und eine weitere Drehachse für Flexion/Extension der Wirbelkörper eingeschränkt werden.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, ein Implantat mit zwei artikulierenden Gelenkstücken zu schaffen, welches zwei Drehachsen aufweist, die windschief zueinander stehen und einen definierten Abstand im Raum aufweisen, so dass die Bewegungen der angrenzenden Wirbelkörper nach Resektion der dazwischenliegenden Bandscheibe durch das Implantat reproduziert werden.

Die Erfindung löst die gestellte Aufgabe mit einem Implantat, vorzugsweise einem Zwischenwirbelimplantat, welches die Merkmale des Anspruchs 1 aufweist

Das erfindungsgemässe Implantat umfasst im wesentlichen zwei Gelenkstücke mit aufeinander artikulierenden Gleitflächen, welche sich bei einer Rotation der Gelenkstücke relativ zueinander aufeinander verschieben. Jedes der Gelenkstücke weist eine im wesentlichen parallel oder koaxial zu den Längsachsen von zwei angrenzenden Knochen verlaufende Zentralachse auf, welche in der Ruhestellung bei entsprechend aufrechter Körperhaltung, d.h. bei nicht gegeneinander abgekippten Gelenkstücken zusammenfallen. Ferner umfassen die Gelenkstücke je ein axial aussenstehendes, mit einem Knochen verbindbares Ende. Bei der Ausgestaltung des Implantates als Zwischenwirbelimplantat sind diese Enden mit den angrenzenden Wirbelkörpern verbindbar, während die Zentralachsen im wesentlichen parallel oder koaxial mit der Wirbelsäulenlängsachse verlaufen. Die Gleitflächen schneiden die Zentralachsen der Gelenkstücke und verschieben sich bei einer Rotation der Gelenkstücke relativ zueinander aufeinander, wobei das zweite Gelenkstück um zwei windschief zueinander angeordnete Drehachsen relativ zum ersten Gelenkstück rotierbar ist.

Im folgenden werden das erste Gelenkstück als feststehend und das zweite Gelenkstück als bewegbar angenommen. Damit sind die Drehachsen gegenüber dem zweiten Gelenkstück feststehend und gegenüber dem ersten Gelenkstück bewegbar.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass dank des erfindungsgemässen Implantates, insbesondere Zwischenwirbelimplantates

- die Lage des Rotationszentrums bei Flexion oder Extension und/oder bei lateraler Biegung der Wirbelkörper besser an die Physiologie angepasst wird;
- die Gleitflächen ohne grosse Reibungskräfte aufeinander verschiebbar sind, und durch Reproduzieren der entsprechenden Hebelarme die Kraftverhältnisse und Momente möglichst minimiert werden; und
- eine Versteifung gegenüber Torsionsbewegungen der Wirbelkörper um die Wirbelsäulenlängsachse erreichbar ist.

In der bevorzugten Ausführungsform des erfindungsgemässen Implantates sind die Gleitflächen sattelförmig ausgestaltet und weisen je einen Sattelpunkt auf. Die sattelförmigen Gleitflächen sind derart ausgestaltet, dass sich in jeder der durch die Abmessungen der Gelenkteile begrenzten Umgebung eines Flächenpunktes P stets zwei Flächenpunkte angeben lassen, welche auf verschiedenen Seiten der Tangentialebene durch den Flächenpunkt P liegen.

In einer weiteren Ausführungsform des erfindungsgemässen Implantates kreuzen sich die Drehachsen unter einem Winkel, welcher vorzugsweise zwischen 80° und 100° beträgt. Dadurch ist der Vorteil erreichbar, dass beispielsweise ein Zwischenwirbelimplantat so implantierbar ist, dass eine der Drehachsen parallel oder koaxial zur Achse für die laterale Biegung Wirbelkörper und die zweite Drehachse parallel oder koaxial zur Achse für die Flexion oder Extension der Wirbelkörper ausgerichtet ist.

In einer anderen Ausführungsform des erfindungsgemässen Implantates weisen die Drehachsen einen minimalen Abstand A relativ zueinander auf, welcher zwischen 0,1

mm und 20 mm, vorzugsweise zwischen 2 mm und 20 mm beträgt. Der Abstand A wird auch durch den Einsatzort des erfindungsgemässen Implantates an der Wirbelsäule mitbestimmt und variiert je nach Segmenthöhe in der lumbalen Wirbelsäule und nimmt in Richtung der thorakalen Wirbelkörper ab.

Vorzugsweise sind die Gleitflächen derart ausgestaltet, dass sich bei einer Drehung des zweiten Gelenkstückes um jede der Drehachsen der zweite Sattelpunkt auf zu den Drehachsen konzentrischen Kreisbogen verschiebt. Die sattelförmige Ausgestaltung der Gleitflächen weist den Vorteil auf, dass auch eine Rotation der Gelenkstücke um die Zentralachsen der Gelenkstücke ermöglicht wird. Jedoch bewegen sich bei einer axialen Rotation der Gelenkstücke relativ zueinander die beiden Gelenkstücke axial voneinander weg, so dass eine axiale Rotation nur bei gleichzeitiger Höhenänderung des Implantates möglich ist. Durch die konstante Vorspannkraft der Bänder, Muskeln und Sehnen in der Wirbelsäule wird eine axiale Rotation der Gelenkstücke nur beschränkt möglich. Dies gilt analog zum physiologischen Fall in der lumbalen Wirbelsäule, wo die axiale Rotation aufgrund der posterioren Elemente, wie Facettengelenke auch nur beschränkt zugelassen wird.

Vorzugsweise sind die Gleitflächen im Ruhezustand der Gelenkstücke betrachtet kongruent ausgebildet. Durch die Ausgestaltung des erfindungsgemässen Implantates mit kongruenten Gleitflächen ist erreichbar, dass eine Torsionsbewegung der Wirbelkörper um die Wirbelsäulenlängsachse ohne Veränderung der Höhe des Zwischenwirbelimplantates nicht möglich ist. Durch eine Veränderung der Höhe des Zwischenwirbelimplantates bei einer solchen Bewegung werden die Bänder angespannt, wodurch ein Widerstand gegen Torsion der Wirbelkörper aufgebracht wird.

In einer weiteren Ausführungsform des erfindungsgemässen Implantates umfassen die aussenstehenden Enden der Gelenkstücke je ein Verbindungsteil, welches mit dem angrenzenden Knochen oder Wirbelkörper verbindbar ist. Bei der Anwendung des erfindungsgemässen Implantates als Zwischenwirbelimplantat sind diese Verbindungsteile vorzugsweise als Deckplatten mit je einer axial aussenstehenden, quer zu den Zentralachsen angeordneten Oberfläche ausgestaltet, wobei diese Oberflächen mit einer dreidimensionalen Strukturierung, beispielsweise mit Finnen ausgestattet sein können.

Dabei kann auch eine der Deckplatten mit dem angrenzenden Gelenkstück einstückig sein.

In einer Ausführungsform des erfindungsgemässen Implantates als Zwischenwirbelimplantat umfasst eine der Deckplatten eine senkrecht zur Zentralachse des angrenzenden Gelenkstücles verlaufende Führung oder Nute, in welche das komplementär zu dieser Führung ausgestaltete, hintere Ende des angrenzenden Gelenkstücles einschiebbar ist. Damit ist der Vorteil erreichbar, dass zuerst die beiden Deckplatten mit dem ersten Gelenkstück aneinanderliegend zwischen die angrenzenden Wirbelkörper geschoben werden können, anschliessend die Deckplatten an die Endflächen der angrenzenden Wirbelkörper gepresst werden können und erst zuletzt das zweite Gelenkstück zwischen das erste Gelenkstück und die zweite Deckplatte eingefügt wird, so dass die Wirbelkörper während der Implantation nur minimal distrahiert werden müssen. Das zweite eingefügte Gelenkstück wird nach dem Einführen an die zweite Deckplatte fixiert.

Die Gelenkstücke können je nach Anwendung als Metall/Metall- Paarung ausgestaltet sein. Ferner sind auch Anwendungen von Kermamikmaterialien geeignet, da wegen der hohen Vorspannkräfte zwischen den angrenzenden Wirbelkörpern in der Wirbelsäule die Belastung der Gelenkstücke auf Schockeinwirkungen gering ist.

In einer weiteren Ausführungsform des erfindungsgemässen Implantates ist eines der Gelenkstücke aus einem Kunststoff hergestellt, so dass

- bereits bewährte Kombinationen von Gelenkersatzmaterialien wie beispielsweise ein hochvernetztes Polyethylen (UHMWPE) und eine Kobalt-Chrom Legierung einsetzbar sind;
- geringe Reibungskräfte bei der Verschiebung der Gleitflächen relativ zueinander erreichbar sind; und
- eine Dämpfung für die Rotationsbewegung der Gelenkstücke um die Zentralachsen herstellbar ist.

In wiederum einer weiteren Ausführungsform des erfindungsgemässen Implantates ist eines der Gelenkstücke um seine Zentralachse rotierbar am zugehörigen Verbindungsteil, respektive an der zugehörigen Deckplatte aufnehmbar. Dazu kann beispielsweise das aussenstehende Ende des Gelenkstücker in einer komplementären, zur Zentralachse coaxialen Vertiefung am zugehörigen Verbindungsteil, respektive der zugehörigen Deckplatte gelagert sein. Andererseits kann das Verbindungsteil mit einer zur Zentralachse coaxialen Erhebung und das Gelenkstück mit einer komplementären Vertiefung versehen sein. Damit ist der Vorteil erreichbar, dass Torsionsbewegungen der beiden angrenzenden Wirbelkörper durch das Implantat nicht verhindert werden.

In einer anderen Ausführungsform des erfindungsgemässen Implantates ist eines der Gelenkstücke parallel zu einer senkrecht zu Zentralachse verlaufenden Verschiebeachse verschiebbar am zugehörigen Verbindungsteil, respektive der zugehörigen Deckplatte aufnehmbar. Vorzugsweise ist das aussenstehende Ende des Gelenkstücker endständig mit einer zur Zentralachse coaxialen Erweiterung versehen, während das zugehörige Verbindungsteil, respektive die zugehörige Deckplatte eine zum aussenstehenden Ende des Gelenkstücker komplementäre Vertiefung mit einem Hinterstich zu Aufnahme der Erweiterung umfasst. Durch diese Ausgestaltung des erfindungsgemässen Implantates sind auch einachsige Scherbewegungen zwischen den beiden an das Implantat angrenzenden Wirbelkörper möglich, ohne dass diese durch das Implantat verhindert werden. Durch die Ausgestaltung der Länge der Vertiefung kann die Scherbewegung der Wirbelkörper innerhalb der gewünschten Begrenzung eingeschränkt werden.

In wiederum einer anderen Ausführungsform des erfindungsgemässen Implantates ist eines der Gelenkstücke in einer zur Zentralachse senkrecht stehenden Ebene verschiebbar am zugehörigen Verbindungsteil, respektive der zugehörigen Deckplatte aufnehmbar. Vorzugsweise weist hierzu das aussenstehende Ende des Gelenkstücker einen kleineren Durchmesser auf als die Vertiefung an dem zugehörigen Verbindungsteil, respektive der zugehörigen Deckplatte. Dadurch ist der Vorteil erreichbar, dass auch Scherbewegungen der an das Implantat angrenzenden Wirbelkörper bezüglich mehrerer Achsen zugelassen werden können.

Weitere vorteilhafte Ausgestaltungen der Erfindung sind in den abhängigen Ansprüchen gekennzeichnet.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1a eine Ansicht einer Ausführungsform des erfindungsgemässen Implantates, wobei das zweite Gelenkstück um die erste Drehachse rotiert ist;

Fig. 1b eine Seitenansicht der in Fig. 1a dargestellten Ausführungsform des erfindungsgemässen Implantates;

Fig. 1c eine Ansicht der in den Fig. 1a und 1b dargestellten Ausführungsform des erfindungsgemässen Implantates, wobei das zweite Gelenkstück um die zweite Drehachse rotiert ist;

Fig. 1d eine Seitenansicht der in Fig. 1c dargestellten Ausführungsform des erfindungsgemässen Implantates;

Fig. 2 eine perspektivische Ansicht des ersten Gelenkstücker einer Ausführungsform des erfindungsgemässen Implantates;

Fig. 3 eine perspektivische Ansicht einer Ausführungsform des erfindungsgemässen Implantates als Zwischenwirbelimplantat;

Fig. 4a eine Ansicht von ventral auf eine Ausführungsform des erfindungsgemässen Implantates;

Fig. 4b eine Ansicht von lateral auf die in Fig. 4a dargestellte Ausführungsform des erfindungsgemässen Implantates.

Fig. 5 eine Ansicht einer weiteren Ausführungsform des erfindungsgemässen Implantates mit relativ zur Zentralachse rotierbar an der Deckplatte angeordnetem Gelenkstück;

Fig. 6a ein Ansicht einer anderen Ausführungsform des erfindungsgemässen Implantates mit in einer zur Zentralachse senkrecht stehenden Ebene verschiebbar angeordnetem Gelenkstück;

Fig. 6b einen Schnitt durch die in Fig. 6a dargestellte Ausführungsform des erfindungsgemässen Implantates;

Fig. 7a eine Ansicht einer weiteren Ausführungsform des erfindungsgemässen Implantates mit senkrecht zur Zentralachse verschiebbar angeordnetem Gelenkstück; und

Fig. 7b einen Schnitt durch die in Fig. 7a dargestellte Ausführungsform des erfindungsgemässen Implantates.

In den Fig. 1a bis 1d ist eine Ausführungsform des erfindungsgemässen Implantates mit einem ersten und einem zweiten Gelenkstück 4;5 dargestellt, wobei in Fig. 1b die beiden Gelenkstücke 4;5 von der Seitenansicht A gezeigt werden. Das erste Gelenkstück 4 weist eine erste Zentralachse 1 und eine erste, diese erste Zentralachse 1 schneidende Gleitfläche 6 auf. Diese erste Gleitfläche 6 ist sattelförmig ausgestaltet und hat einen ersten Sattelpunkt 8. Analog zum ersten Gelenkstück 4 weist das zweite Gelenkstück 5 eine zweite Zentralachse 26 und eine zweite, diese zweite Zentralachse 26 schneidende Gleitfläche 7 auf. Auch die zweite Gleitfläche 7 ist sattelförmig ausgestaltet und weist den Sattelpunkt 9 auf. Ferner umfassen die Gelenkstücke 4;5 aussenstehende Enden 14;15, welche an den Endflächen von an die Gelenkstücke angrenzenden Knochen, insbesondere von angrenzenden Wirbelkörpern zur Anlage bringbar sind. In einer zur Zentralachse 1 orthogonalen Ebene betrachtet schneiden sich die Projektionen der Drehachsen 10;11 in diese Ebene unter einem Winkel von 90°. Der minimale Abstand A ist bei dieser Ausgestaltung der Gleitflächen 6;7 die Senkrechte auf den beiden Drehachsen 10;11. In den Fig. 1a und 1b ist das zweite Gelenkstück 5 um die erste Drehachse 10 (Fig. 1b) rotiert. Der zweite Sattelpunkt 9 wird

bei der Rotationsbewegung des zweiten Gelenkstückes 5 um den Winkel β auf einem zur ersten Drehachse 10 konzentrischen Kreisbogen mit dem Radius R_1 verschoben.

Die Fig. 1c und 1d zeigen die Gelenkstücke 4;5 der in den Fig. 1a und 1b dargestellten Ausführungsform des erfindungsgemässen Implantates, wobei das zweite Gelenkstück 5 um die zweite Drehachse 11 (Fig. 1c) um den Winkel α rotiert ist. Bei dieser Rotation des zweiten Gelenkstückes 5 um die zweite Drehachse 11 wird der zweite Sattelpunkt 9 auf einem zur zweiten Drehachse 11 konzentrischen Kreisbogen mit dem Radius R_2 verschoben.

In Fig. 2 ist das erste Gelenkstück 4 mit einer sattelförmig ausgestalteten ersten Gleitfläche 6 dargestellt. Die beiden Drehachsen 10;11 sind in der Ruhelage des erfindungsgemässen Implantates bei entsprechend aufrechter Körperhaltung dargestellt, d.h. die Zentralachse 1 des ersten Gelenkstückes 4 fällt mit der Zentralachse 26 des zweiten Gelenkstückes 5 (Fig. 1) zusammen. In der Ruhelage stehen die Drehachsen 10;11 senkrecht auf der Zentralachse 1 und liegen in Ebenen 22;23. Die erste Drehachse 10 steht senkrecht auf einer ersten Ebene 22, welche durch die Zentralachse 1 und die zweite Drehachse 11 aufgespannt wird. Die zweite Drehachse 11 steht senkrecht auf einer zweiten, zur ersten Ebene 22 senkrecht stehenden Ebene 23, welche durch die Zentralachse 1 und die erste Drehachse 10 aufgespannt wird. Der erste Sattelpunkt 8 der ersten Gleitfläche 6 liegt in der Ruhelage sowohl auf der Zentralachse 1 wie auch auf zwei Kreisbogen 24;25, deren Zentrum in der Ruhelage der Gelenkstücke 4;5 durch den Schnittpunkt der Zentralachse 1 mit je einer der Drehachsen 10;11 definiert ist. Die erste Gleitfläche 6 schmiegt sich einerseits an den ersten, zur ersten Drehachse 10 konzentrischen Kreisbogen 24 und andererseits auch an den zweiten, zur zweiten Drehachse 11 konzentrischen Kreisbogen 25. Die Radien R_1 des ersten Kreisbogens 24 und R_2 des zweiten Kreisbogens 25 sind bei kongruenten Gleitflächen 7;8 gleich gross und entsprechen dem halben Abstand A der beiden Drehachsen 10;11.

Die Gleitfläche 6 ist derart ausgestaltet, dass sie die komplementäre Form eines Ausschnittes aus einer Torusoberfläche darstellt.

In Fig. 3 ist eine Ausführungsform des erfindungsgemässen Implantates als Zwischenwirbelimplantat dargestellt. Die beiden Gelenkstücke 4;5 umfassen an ihren aussenstehenden Enden 14;15 als Verbindungsteile 2;3 je eine Deckplatte 12;13, mit bezüglich den Zentralachsen 1;26 axial aussenstehenden und quer zu den Zentralachsen 1;26 stehenden Oberflächen 16;17, welche an die Endflächen der angrenzenden Wirbelkörper zur Anlage bringbar sind. Die Deckplatten 12;13 weisen je zwei laterale Seitenflächen 27, eine anteriore Seitenfläche 28 und eine posteriore Seitenfläche 29 auf, wobei die lateralen Seitenfläche 27 im wesentlichen parallel zur ersten Drehachse 10 angeordnet sind. Die anteriore sowie die posteriore Seitenfläche 28;29 sind im wesentlichen parallel zur zweiten Drehachse 11 angeordnet. Das Implantat wird so zwischen die angrenzenden Wirbelkörper (nicht gezeichnet) eingeführt, dass eine Rotation der Gelenkstücke 4;5 um die erste Drehachse 10 eine laterale Biegung der mit dem Implantat verbundenen Wirbelkörper ermöglicht, während eine Rotation der Gelenkstücke 4;5 um die zweite Drehachse 11 eine Flexion respektive Extension der mit dem Implantat verbundenen Wirbelkörper gestattet. In der hier dargestellten Ausführungsform des erfindungsgemässen Implantates ist die erste Deckplatte 12 mit dem ersten Gelenkstück 4 fest verbunden, während die zweite Deckplatte 13 eine senkrecht zur Zentralachse 26 stehende und im wesentlichen parallel zur den lateralen Seitenflächen 27 angeordnete, als Nute ausgebildete Führung 20 aufweist, so dass das zweite Gelenkstück 5 mit seinem aussenstehenden, zur Führung 20 komplementär ausgebildeten Ende 15 in die Führung 20 einschiebbar ist. Ferner sind auf den aussenstehenden Oberflächen 16;17 der Deckplatten 12;13 Finnen 19 angebracht, welche zur primären Stabilisation des Implantates an den angrenzenden Wirbelkörpern dienen.

Die in den Fig. 4a und 4b dargestellte Ausführungsform des erfindungsgemässen Implantates unterscheidet sich von der in Fig. 3 gezeigten Ausführungsform des erfindungsgemässen Implantates nur darin, dass sie keine Finnen 19 umfasst und dass die Gelenkstücke 4;5 nur innerhalb begrenzter Drehwinkel α und β um die Drehachsen 10;11 rotierbar sind. In Fig. 4a ist das Implantat von ventral, d.h. parallel zur Drehachse 10 betrachtet gezeigt und in Fig. 4b ist das Implantat von lateral, d.h. parallel zur Drehachse 11 betrachtet dargestellt (Fig. 4b). Die Begrenzung der Drehwinkel α und β wird durch die Wahl der Abmessungen H_L ; H_A ; H_P ; R_1 ; R_2 ; h_1 und h_2 an den Gelenkstücken 4; 5 hergestellt, wobei bei Erreichen des gewünschten maximalen

Drehwinkels α oder β die jeweils gegen das andere Gelenkstück 4;5 gerichteten Enden 32; 33; 34 der Gelenkstücke 4;5 auf den Innenflächen 30;31 der dem jeweiligen Gelenkstück 4;5 gegenüberliegenden Deckplatte 12;13 anstehen und

H_L : die Höhe zwischen dem ersten Sattelpunkt 8 und den inneren, gegen das zweite Gelenkstück 5 gerichteten Enden 32 des ersten Gelenkstücles 4 ist;

H_A : die Höhe zwischen dem zweiten Sattelpunkt 9 und dem anterioren, gegen das erste Gelenkstück 4 gerichteten Ende 34 des zweiten Gelenkstücles 5 ist;

H_P : die Höhe zwischen dem zweiten Sattelpunkt 9 und dem posterioren, gegen das erste Gelenkstück 4 gerichteten Ende 33 des zweiten Gelenkstücles 5 ist;

R_1 : der Radius der ersten Gleitfläche 6 in der ersten, zur ersten Drehachse 10 senkrechten und den ersten Sattelpunkt 8 enthaltenden Ebene 22 (Fig. 2) ist;

R_2 : der Radius der zweiten Gleitfläche in der zweiten, zur zweiten Drehachse 11 senkrechten und den zweiten Sattelpunkt 9 enthaltenden Ebene 23 (Fig. 2) ist;

h_1 : die Höhe zwischen dem ersten Sattelpunkt 8 und der Innenfläche 31 der ersten Deckplatte 12 ist; und

h_2 : die Höhe zwischen dem zweiten Sattelpunkt 9 und der Innenfläche 30 der zweiten Deckplatte 13 ist.

In Fig. 5 ist eine Ausführungsform des erfindungsgemässen Implantates dargestellt, welche sich von den in den Fig. 1 bis 4 dargestellten Ausführungsformen darin unterscheidet, dass das aussenstehende Ende 14 des ersten Gelenkstücles 4 in einer komplementären, zur Zentralachse 1 coaxialen Vertiefung 37 in der Deckplatte 12 aufgenommen wird, so dass das erste Gelenkstück 4 um die Zentralachse 1 rotierbar mit der Deckplatte 12 zusammenfügbar ist.

In den Fig. 6a und 6b ist eine Ausführungsform des erfindungsgemässen Implantates dargestellt, welche sich von der in Fig. 5 dargestellten Ausführungsformen nur darin

unterscheidet, dass die Vertiefung 37 zur Zentralachse 1 einen grösseren Durchmesser aufweist als das aussenstehende Ende 14 des ersten Gelenkstückes 4, so dass das erste Gelenkstück 4 in einer zur Zentralachse 1 senkrecht stehenden Ebene relativ zur Deckplatte 12 verschiebbar ist.

In den Fig. 7a und 7b ist eine Ausführungsform des erfindungsgemässen Implantates dargestellt, welche sich von der in Fig. 5 dargestellten Ausführungsform nur darin unterscheidet, dass die Vertiefung 37 parallel zu einer senkrecht zur Zentralachse 1 stehenden Verschiebeachse 40 oval ausgestaltet ist und einen Hinterstich 39 aufweist, während das aussenstehende Ende 14 des ersten Gelenkstückes 4 endständig eine zur Zentralachse 1 koaxiale Erweiterung 38 umfasst, welche in den Hinterstich 39 eingreift, so dass das erste Gelenkstück 4 einerseits parallel zur Verschiebeachse 40 verschiebbar und andererseits durch die in den Hinterstich 39 eingreifende Erweiterung 38 bezüglich der Zentralachse 1 axial gesichert ist.

Patentansprüche

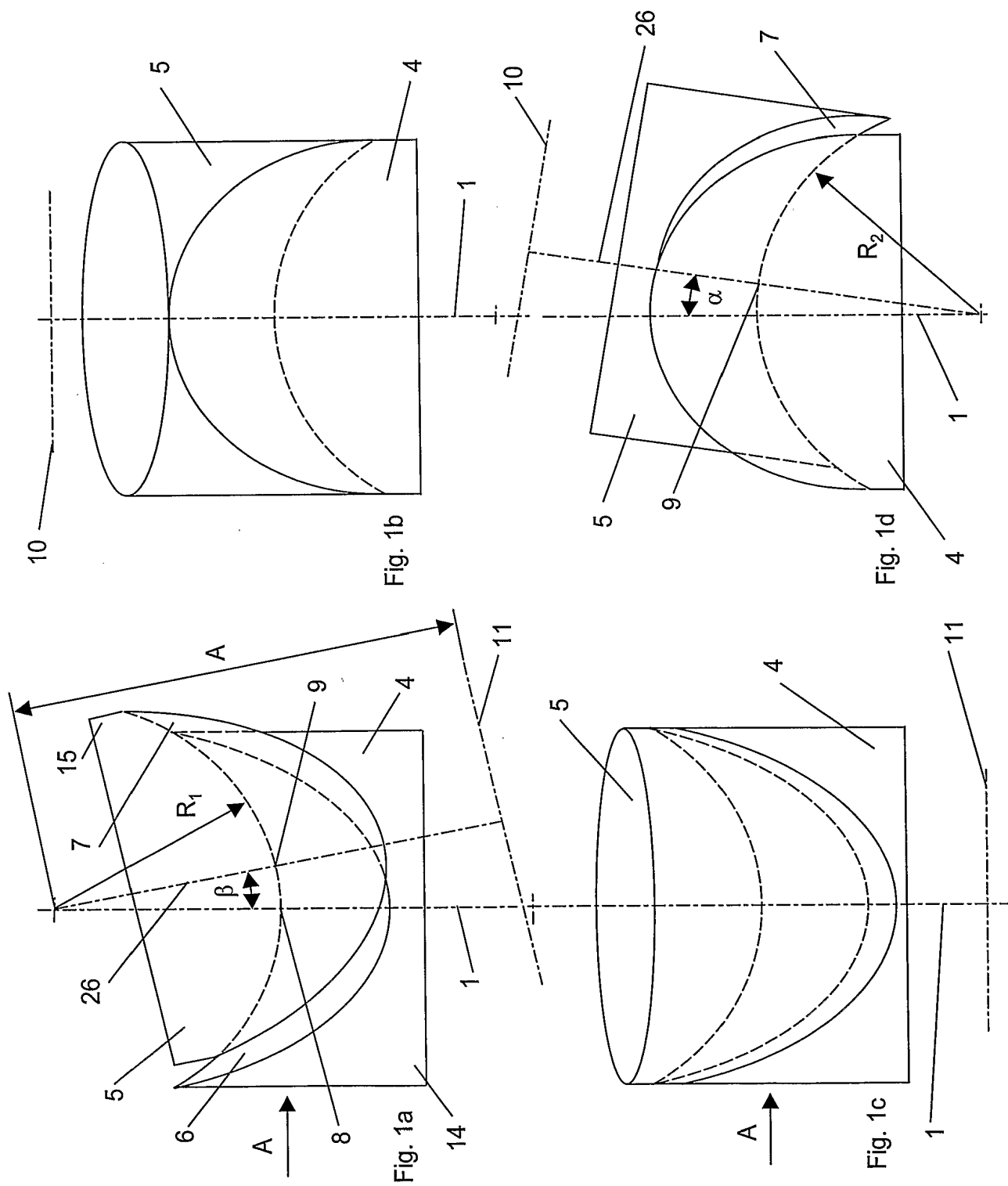
1. Implantat, insbesondere Zwischenwirbelimplantat mit
 - A) zwei Gelenkstücken (4;5), welche je eine Zentralachse (1;26), je eine die Zentralachsen (1;26) schneidende Gleitfläche (6;7) und je ein axial aussenstehendes, mit einem Knochen verbindbares Ende (14;15) aufweisen, wobei
 - B) die Gleitflächen (6;7) gekrümmt ausgebildet sind, dadurch gekennzeichnet, dass
 - C) die Gleitflächen aufeinander verschiebbar sind; und
 - D) das zweite Gelenkstück (5) um zwei windschief angeordnete Drehachsen (10;11) relativ zum ersten Gelenkstück (4) rotierbar ist.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, dass die Gleitflächen (6;7) sattelförmig ausgestaltet sind.
3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Drehachsen (10;11) sich unter einem Winkel zwischen 80° und 100° kreuzen.
4. Implantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Drehachsen (10;11) einen minimalen Abstand A relativ zueinander aufweisen und dass dieser Abstand A zwischen 0,1 mm und 20 mm beträgt.
5. Implantat nach Anspruch 4, dadurch gekennzeichnet, dass der Abstand A zwischen 2 mm und 20 mm beträgt.
6. Implantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Gleitflächen (6;7) je einen Sattelpunkt (8;9) aufweisen, wobei sich bei einer Drehung des zweiten Gelenkstückes (5) um jede der Drehachsen (10;11) der zweite Sattelpunkt (9) auf einem zu der jeweiligen Drehachse (10;11) konzentrischen Kreisbogen (12;14) verschiebt.
7. Implantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Gleitflächen (6;7) in der Ausgangsstellung bei coaxialen Zentralachsen (1;26) der Gelenkstücke (4;5) kongruent ausgestaltet sind.

8. Implantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass die aussenstehenden Enden (14;15) der Gelenkstücke (4;5) je ein Verbindungsteil (2;3) umfassen.
9. Implantat nach Anspruch 8, dadurch gekennzeichnet, dass die Verbindungsteile (2;3) als Deckplatten (12;13) mit je einer axial aussenstehenden, quer zu den Zentralachsen (1;26) angeordneten Oberfläche (16;17) ausgestaltet sind.
10. Implantat nach Anspruch 9, dadurch gekennzeichnet, dass eine der Deckplatten (12;13) mit dem angrenzenden Gelenkstück (5) einstückig ist.
11. Implantat nach Anspruch 9 oder 10, dadurch gekennzeichnet, dass eine der Deckplatten (12) eine senkrecht zur Zentralachse (1) verlaufende Führung (20) umfasst, und dass das angrenzende Gelenkstück (4) ein hinteres Ende (14) aufweist, welches in die Führung (20) einschiebbar ist.
12. Implantat nach einem der Ansprüche 8 bis 11, dadurch gekennzeichnet, dass eines der Gelenkstücke (4;5) um dessen Zentralachse (1;26) rotierbar mit dem zugehörigen Verbindungsteil (2;3) zusammenfügbar ist.
13. Implantat nach einem der Ansprüche 8 bis 12, dadurch gekennzeichnet, dass eines der Gelenkstücke (4;5) auf einer senkrecht zu dessen Zentralachse (1;26) stehenden Verschiebeachse (40) verschiebbar mit dem zugehörigen Verbindungsteil (2;3) zusammenfügbar ist.
14. Implantat nach einem der Ansprüche 8 bis 13, dadurch gekennzeichnet, dass eines der Gelenkstücke (4;5) in einer senkrecht zu dessen Zentralachse (1;26) stehenden Ebene verschiebbar mit dem zugehörigen Verbindungsteil (2;3) zusammenfügbar ist.
15. Implantat nach einem der Ansprüche 12 bis 14, dadurch gekennzeichnet, dass ein Verbindungsteil (2;3) eine zur Zentralachse (1;26) koaxiale Vertiefung (37) zur Aufnahme des aussenstehenden Endes (14;15) des angrenzenden Gelenkstückes (4;5) aufweist.

16. Implantat nach Anspruch 15, dadurch gekennzeichnet, dass die Vertiefung (37) axial endständig einen Hinterstich (39) aufweist, und dass das aussenstehende Ende (14;15) des angrenzenden Gelenkstückes (4;5) eine zur Zentralachse (1;26) koaxiale Erweiterung (38) aufweist, welche im Hinterstich (39) aufnehmbar ist.

17. Implantat nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass eines der Gelenkstücke (4;5) aus einem Kunststoff hergestellt ist.

18. Implantat nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, dass mindestens eines der Gelenkstücke (4;5) aus einem Keramikmaterial besteht.



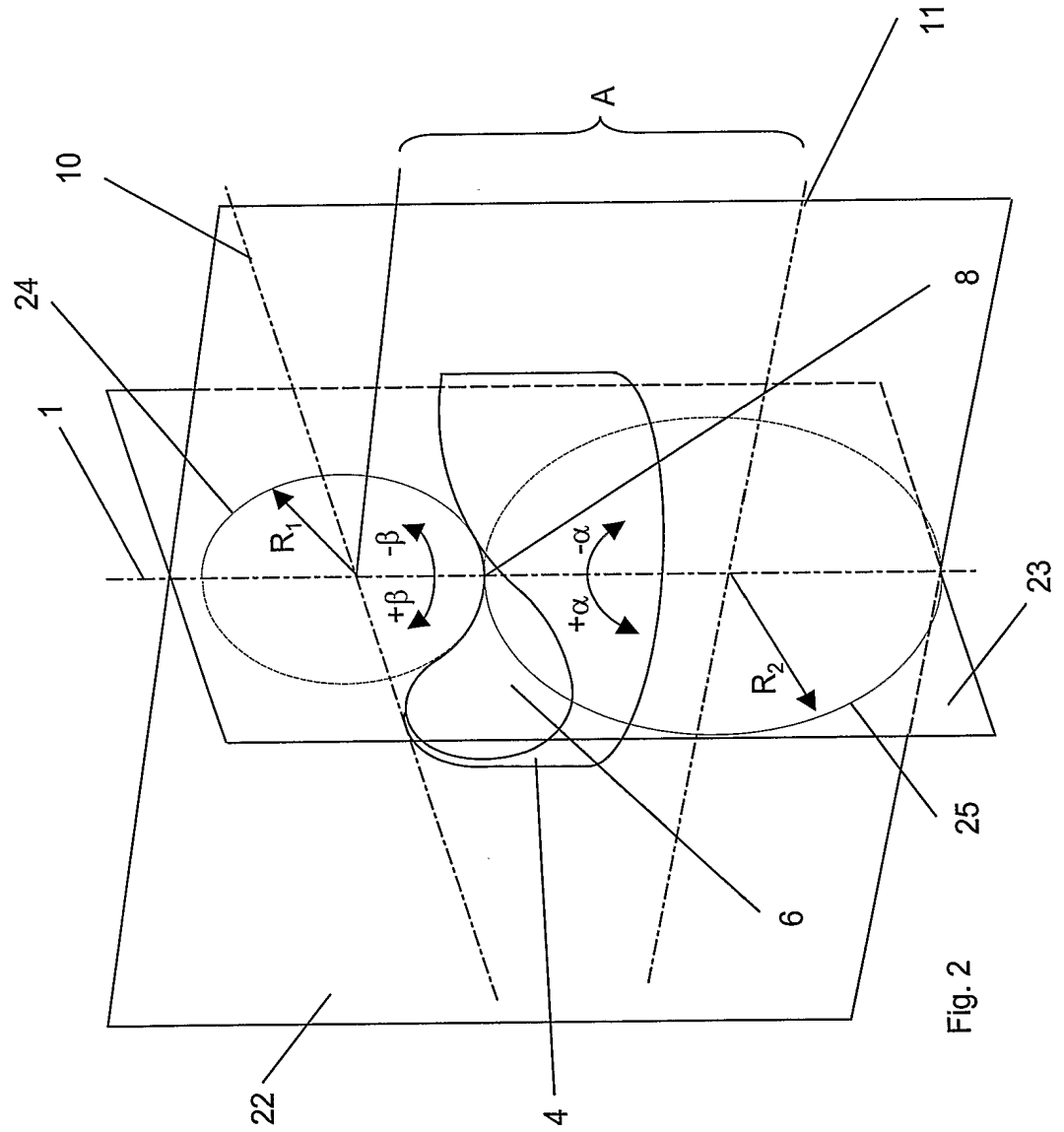


Fig. 2

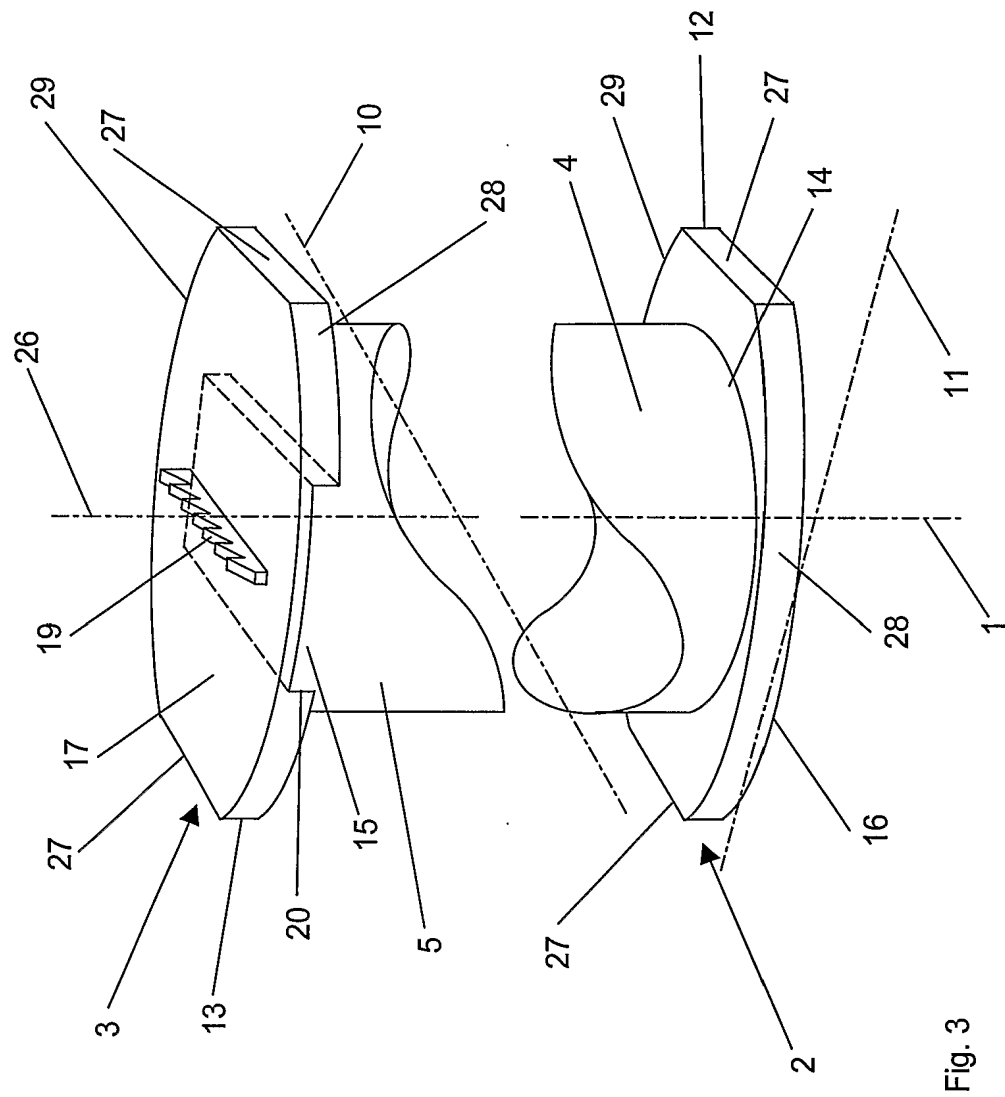
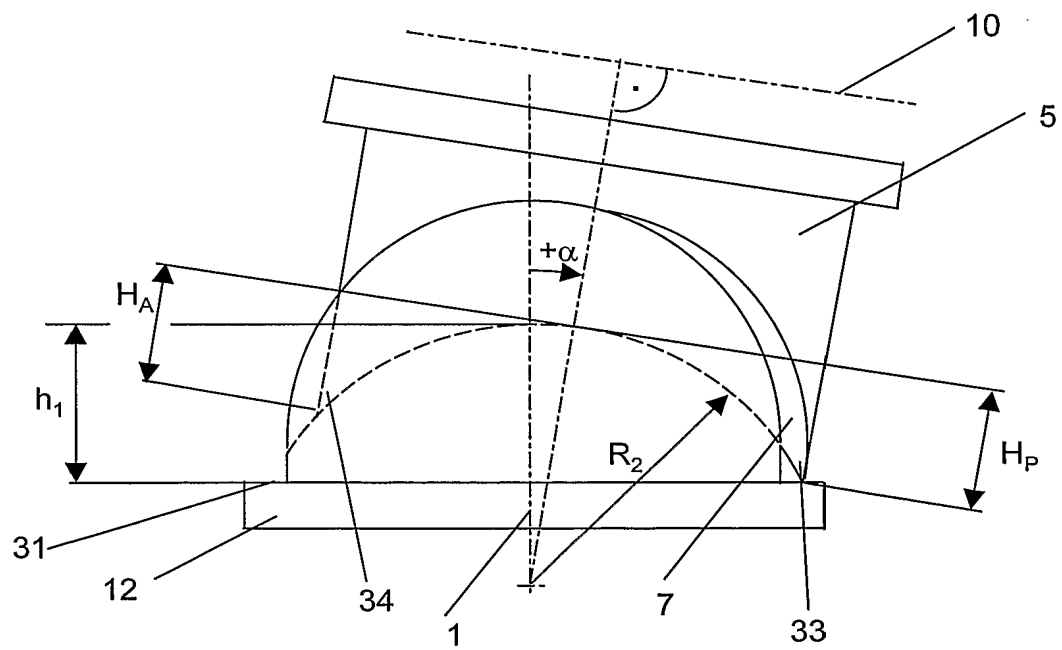
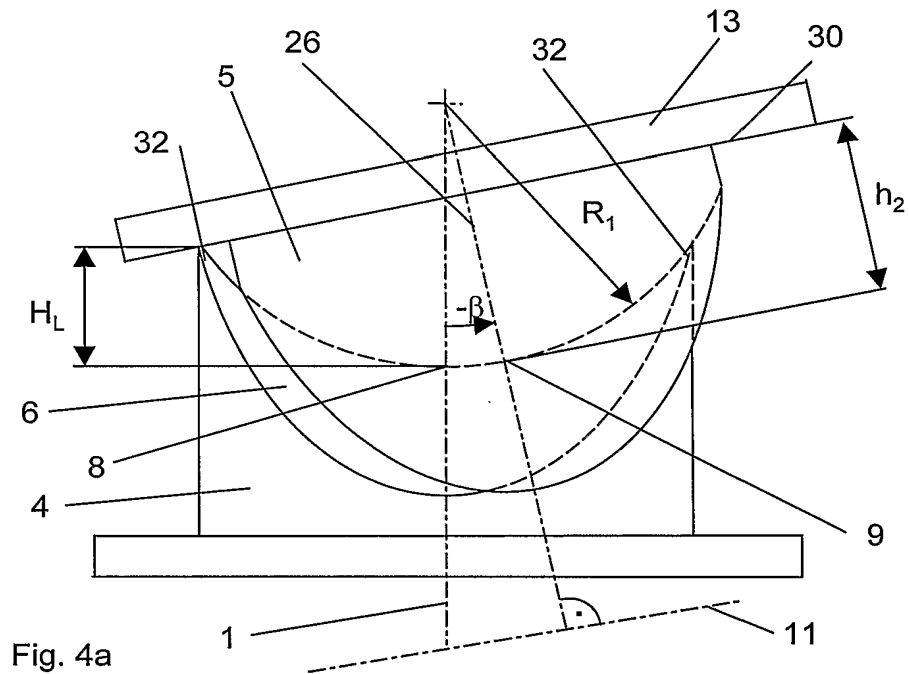


Fig. 3

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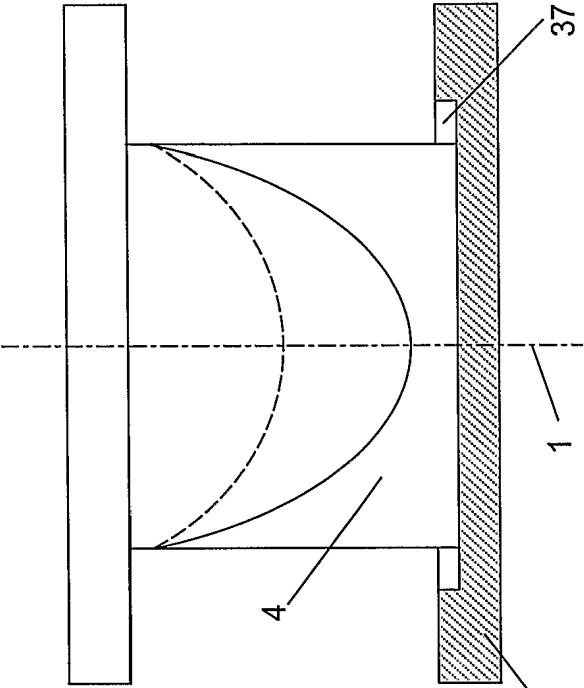


Fig. 6a

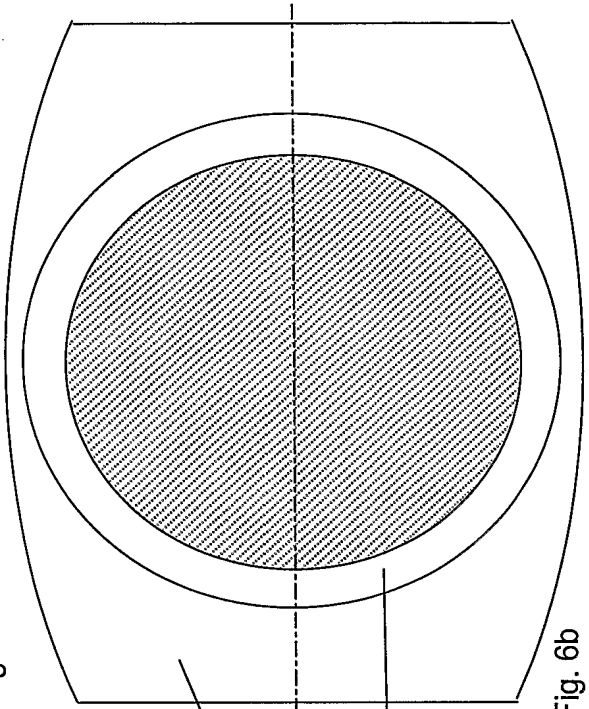


Fig. 6b

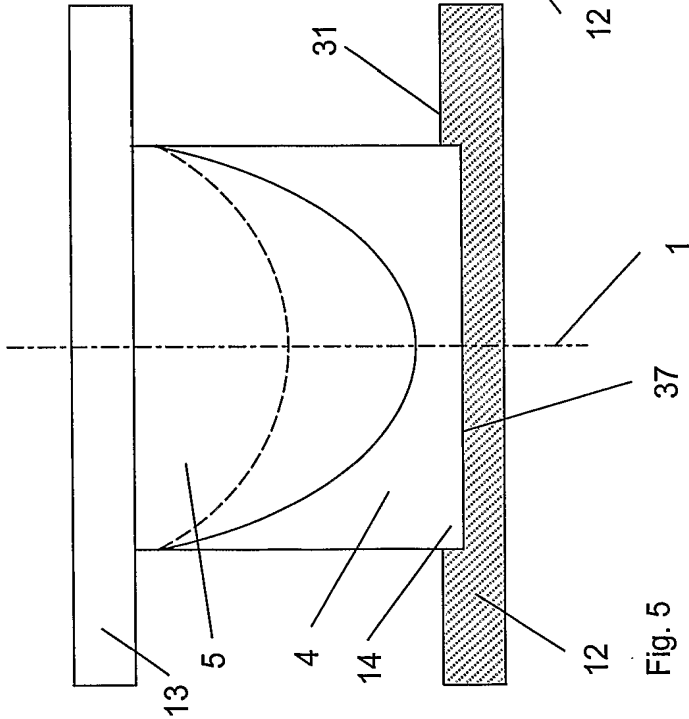
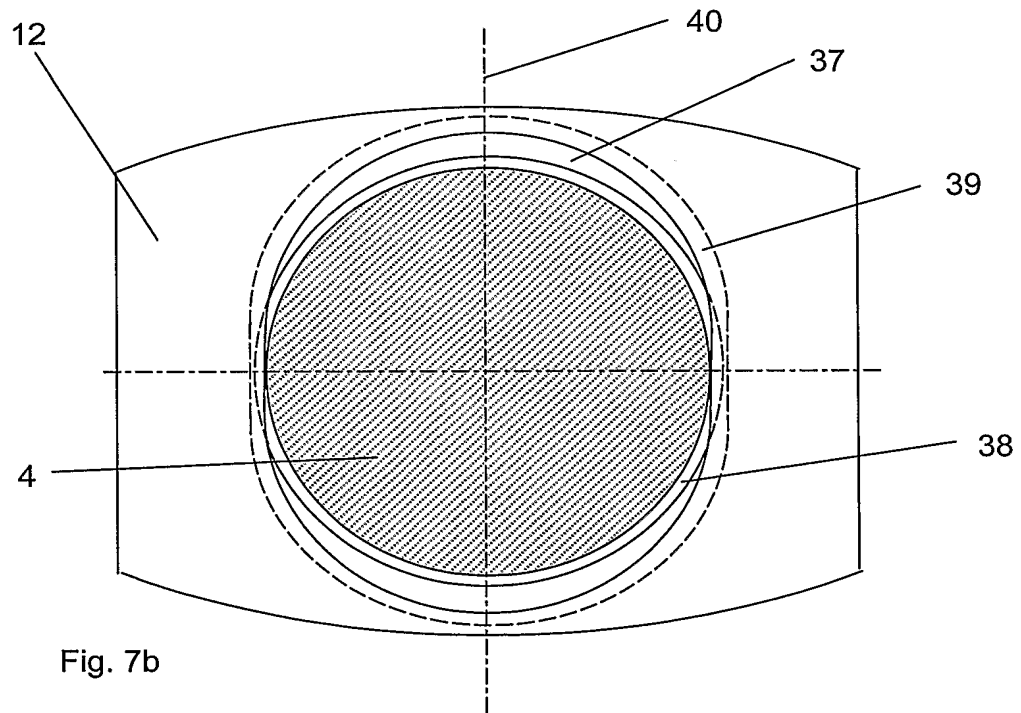
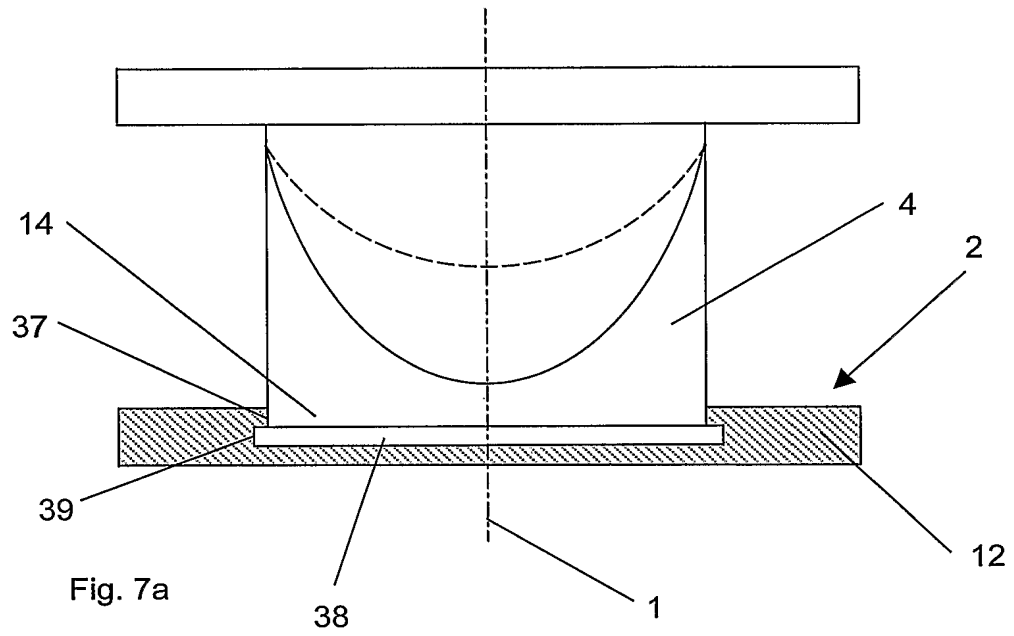


Fig. 5

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 02/00512

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 605 A (KLAITTER JEROME) 8 July 1997 (1997-07-08) figures column 4, line 11 - column 7, line 10 ---	1-8, 17, 18
X	US 6 368 350 B1 (GRIFFITH STEVEN L ET AL) 9 April 2002 (2002-04-09) abstract; figures 5-32 column 5, line 53 - line 65 ---	1, 3, 7-10, 12-15, 17, 18
X	US 5 405 400 A (LINSCHIED RONALD L ET AL) 11 April 1995 (1995-04-11) abstract; figures column 4, line 15 - line 38 column 5, line 56 - line 61 --- -/--	1-8, 17

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Date of the actual completion of the international search

30 May 2003

Date of mailing of the international search report

10/06/2003

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 02/00512

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) figures 1,7 page 12, paragraph 3 -----	1,3, 7-11, 15-17
X	US 6 290 726 B1 (GARDINIER CLAYTON F ET AL) 18 September 2001 (2001-09-18) figure 2AA column 19, line 4 - line 15 -----	1,6,7,18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH 02/00512

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5645605	A	08-07-1997	AT 187318 T DE 69605564 D1 DE 69605564 T2 EP 0854695 A1 ES 2141533 T3 JP 2000510351 T WO 9710780 A1	15-12-1999 13-01-2000 13-07-2000 29-07-1998 16-03-2000 15-08-2000 27-03-1997
US 6368350	B1	09-04-2002	AU 3873000 A WO 0053127 A1	28-09-2000 14-09-2000
US 5405400	A	11-04-1995	AU 680559 B2 AU 7927794 A CA 2173581 A1 EP 0726746 A1 JP 9506009 T WO 9509587 A1	31-07-1997 01-05-1995 13-04-1995 21-08-1996 17-06-1997 13-04-1995
WO 0101893	A	11-01-2001	DE 29911422 U1 WO 0101893 A1 AU 7224500 A BR 9917397 A CA 2391330 A1 EP 1194088 A1 JP 2003503154 T	12-08-1999 11-01-2001 22-01-2001 05-03-2002 11-01-2001 10-04-2002 28-01-2003
US 6290726	B1	18-09-2001	US 6497727 B1 US 6402787 B1 US 6398815 B1 US 6494918 B1 US 6425922 B1 US 6514289 B1 US 6517583 B1 WO 0154627 A1 US 6488715 B1 AU 3463201 A AU 3656501 A AU 3656901 A AU 3657801 A AU 3798201 A AU 3798301 A CA 2399015 A1 EP 1253870 A2 WO 0154561 A2 WO 0154612 A2 WO 0154613 A2 WO 0154628 A1 WO 0155476 A1	24-12-2002 11-06-2002 04-06-2002 17-12-2002 30-07-2002 04-02-2003 11-02-2003 02-08-2001 03-12-2002 07-08-2001 07-08-2001 07-08-2001 07-08-2001 07-08-2001 07-08-2001 02-08-2001 06-11-2002 02-08-2001 02-08-2001 02-08-2001 02-08-2001 02-08-2001

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

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A. KLASSTIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

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IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 645 605 A (KLAWITTER JEROME) 8. Juli 1997 (1997-07-08) Abbildungen Spalte 4, Zeile 11 - Spalte 7, Zeile 10 ---	1-8, 17, 18
X	US 6 368 350 B1 (GRIFFITH STEVEN L ET AL) 9. April 2002 (2002-04-09) Zusammenfassung; Abbildungen 5-32 Spalte 5, Zeile 53 - Zeile 65 ---	1, 3, 7-10, 12-15, 17, 18
X	US 5 405 400 A (LINSCHIED RONALD L ET AL) 11. April 1995 (1995-04-11) Zusammenfassung; Abbildungen Spalte 4, Zeile 15 - Zeile 38 Spalte 5, Zeile 56 - Zeile 61 --- -/--	1-8, 17



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Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11. Januar 2001 (2001-01-11) Abbildungen 1,7 Seite 12, Absatz 3 -----	1,3, 7-11, 15-17
X	US 6 290 726 B1 (GARDINIER CLAYTON F ET AL) 18. September 2001 (2001-09-18) Abbildung 2AA Spalte 19, Zeile 4 - Zeile 15 -----	1,6,7,18

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
US 5645605	A	08-07-1997	AT 187318 T	15-12-1999
			DE 69605564 D1	13-01-2000
			DE 69605564 T2	13-07-2000
			EP 0854695 A1	29-07-1998
			ES 2141533 T3	16-03-2000
			JP 2000510351 T	15-08-2000
			WO 9710780 A1	27-03-1997
US 6368350	B1	09-04-2002	AU 3873000 A	28-09-2000
			WO 0053127 A1	14-09-2000
US 5405400	A	11-04-1995	AU 680559 B2	31-07-1997
			AU 7927794 A	01-05-1995
			CA 2173581 A1	13-04-1995
			EP 0726746 A1	21-08-1996
			JP 9506009 T	17-06-1997
			WO 9509587 A1	13-04-1995
WO 0101893	A	11-01-2001	DE 29911422 U1	12-08-1999
			WO 0101893 A1	11-01-2001
			AU 7224500 A	22-01-2001
			BR 9917397 A	05-03-2002
			CA 2391330 A1	11-01-2001
			EP 1194088 A1	10-04-2002
			JP 2003503154 T	28-01-2003
US 6290726	B1	18-09-2001	US 6497727 B1	24-12-2002
			US 6402787 B1	11-06-2002
			US 6398815 B1	04-06-2002
			US 6494918 B1	17-12-2002
			US 6425922 B1	30-07-2002
			US 6514289 B1	04-02-2003
			US 6517583 B1	11-02-2003
			WO 0154627 A1	02-08-2001
			US 6488715 B1	03-12-2002
			AU 3463201 A	07-08-2001
			AU 3656501 A	07-08-2001
			AU 3656901 A	07-08-2001
			AU 3657801 A	07-08-2001
			AU 3798201 A	07-08-2001
			AU 3798301 A	07-08-2001
			CA 2399015 A1	02-08-2001
			EP 1253870 A2	06-11-2002
			WO 0154561 A2	02-08-2001
			WO 0154612 A2	02-08-2001
			WO 0154613 A2	02-08-2001
			WO 0154628 A1	02-08-2001
			WO 0155476 A1	02-08-2001

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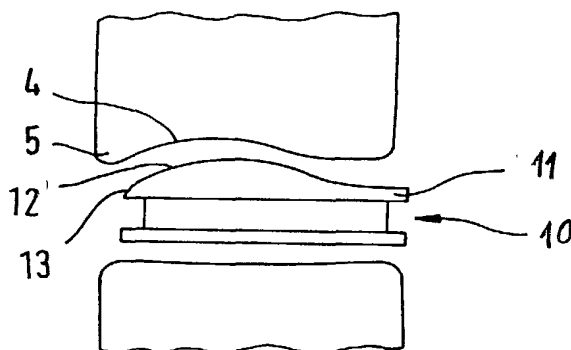
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(54) Title: INTERVERTEBRAL PROSTHESIS

(54) Bezeichnung: ZWISCHENWIRBELPROTHESE



(57) Abstract: Disclosed is an intervertebral prosthesis (10) comprising at least one cover plate (11) that is to be connected in a fixed manner to a vertebra (1) so as to be in contact therewith. In order to prevent the prosthesis (10) from contributing to breaking off a protruding bone edge (5) during insertion or the useful life thereof, the cover plate (11) is provided with a curvature (12) corresponding to the concave shape (4) and/or a sloping, shortened, or rounded section (13) on the edge.

(57) Zusammenfassung: Zwischenwirbelprothese (10) mit wenigstens einer in Anlage an einem Wirbelkörper (1) fest mit diesem zu verbindenden Deckplatte (11). Um zu verhindern, dass die Prothese (10) beim Einsetzen oder während ihrer Lebensdauer dazu beiträgt, dass ein vorstehender Knochenrand (5) abbricht, ist die Deckplatte (11) mit einer der Mulde (4) entsprechenden Vorwölbung (12) und/oder einer Abschrägung, Kürzung oder Abrundung (13) am Rand versehen.

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

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Zwischenwirbelprothese

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Die Deckplatten der Wirbelkörper, zwischen denen sich die Bandscheiben der Wirbelsäule befinden, sind in der Regel eben oder schwach konkav. Mitunter tritt eine verstärkte Konkavität der Deckplatten auf, insbesondere im Bereich der unteren Wirbelsäule. Dies muß nicht, kann aber schadensbedingt sein. Beispielsweise kommt es vor, daß nach einem Bandscheibenvorfall der Rand eines Wirbelkörpers auf die Deckplatte des benachbarten Wirbelkörpers trifft und dort eine Mulde ausschleift. Wie auch immer die verstärkte Konkavität entstanden ist, führt sie zu einer unzureichenden Abstützung des dorsalen Randes, von dem gegebenenfalls auch Osteophyten vorspringen können. Wird nun in den Zwischenwirbelraum eine Prothese eingebracht, so geschieht es leicht, daß deren dorsale Kante gegen den unzureichend abgestützten Rand des Wirbelkörpers oder gegen Osteophyten stößt und dadurch ein Teil des Knochens zum Markkanal hin abbricht, wo er das Rückenmark gefährdet. Dasselbe kann auch dann noch geschehen, wenn die Prothese implantiert ist und wegen ihrer mangelhaften Stützung im Bereich der Mulde den Wirbelkörperperrand zu stark belastet.

Auch bei normal gestalteten Wirbelkörpern kann es geschehen, daß der Rand der Wirbelkörperdeckplatte beim Einschieben ei-

ner Zwischenwirbelprothese von deren Kante so stark beansprucht wird, daß er beschädigt wird.

Der Erfindung liegt die Aufgabe zugrunde, in derartigen Fällen das Abbrechen von Teilen des Wirbelkörpers zu vermeiden. Zur erstmaligen Lösung dieses Problems bietet die Erfindung unterschiedliche Möglichkeiten, nämlich diejenigen nach den Ansprüchen 1, 5, 8, 13, 14 und 15 sowie deren Unteransprüchen.

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Die erste Lösung besteht darin, daß die Zwischenwirbelprothese auf ihrer dem Wirbelkörper zugewendeten Deckplattenoberfläche eine Vorwölbung aufweist, die sich in eine Knochenmulde des Wirbelkörpers legt, um einerseits dort eine verbesserte Abstützung der Prothese zu finden und andererseits den neben der Mulde vorstehenden Knochenrand zu schonen. Diese Vorwölbung erhebt sich über die ansonsten ebene oder in Anpassung an die natürliche Wirbelform höchstens schwach gewölbte Grundform der Deckplattenoberfläche. Die Vorwölbung zeigt sich im Vergleich mit der ebenen oder nur schwach konkaven Form der Wirbelkörperdeckplatten oder im Vergleich mit für normale Anwendungsfälle bestimmten Prothesendeckplatten.

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Wenn die verstärkte Konkavität oder Ausmuldung nur einen Teil der Knochenoberfläche betrifft, weist entsprechend auch die Vorwölbung vorteilhafterweise eine geringere Ausdehnung als die Deckplattenoberfläche in AP- und/oder LM-Richtung auf. Sie liegt vorzugsweise dem dorsalen Rand der Deckplattenoberfläche näher als deren ventralem Rand. Es versteht sich, daß die Vorwölbung nach Höhe, Ausdehnung und Lage möglichst weitgehend an die vorgefundene Wirbelform angenähert sein sollte. Dabei erweist es sich im allgemeinen als zweckmäßig, wenn die

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Vorwölbung bis an die dorsale Kante der Deckplattenoberfläche heranreicht.

Die Vorwölbung soll möglichst weitgehend der Form der von ihr
5 einzunehmenden Mulde angenähert sein. Oftmals reichen dafür einfache geometrische Formen aus, z.B. diejenigen eines Zylinderschnitts mit einer quer liegenden Achsrichtung, eines Kugelschnitts oder eines Abschnitts eines Ellipsoids.

10 Gemäß einem verwandten Lösungsansatz der Erfindung ist der Rand der dem Wirbelkörper zugewandten Deckplattenoberfläche abgeschrägt oder abgerundet. Dadurch erreicht man, daß der Prothesenrand beim Einschieben der Prothese nicht scharf und hart gegen den dorsalen Knochenrand kantet sondern an ihm
15 entlang gleitet. Außerdem wird der Knochenrand von der Kraftübertragung zu Lasten anderer, tragfähigerer Bereiche entlastet. Diese Ausführungsform der Prothese findet vor allem dann Anwendung, wenn die Ausmuldung nicht stark ist und/oder durch Knochenzement ausgefüllt werden kann. Diese
20 Ausführungsform kann auch dann zweckmäßig sein, wenn der Wirbelkörper normal gestaltet ist und lediglich die Gefahr einer zu starken Beanspruchung des Randes des Wirbelkörpers durch eine Prothesenkante vermieden werden soll. Diese Ausführungsform kann auch mit der zuvor erwähnten Vorwölbung kombiniert
25 werden. Die Vorwölbung bildet dann die Abschrägung bzw. Abrundung oder geht in sie über. Die Abschrägung oder Abrundung ist vor allem an der dorsalen Seite von Interesse, aber kann auch an den anderen Seiten der Prothese von Vorteil sein.

30 Die Erfindung hat weiter erkannt, daß die Zähne oder Vorsprünge, die an der Deckplatte der Prothese vorgesehen sind, um in den Knochen einzudringen und sich dort zu verankern, zu

der Schädigung des geschwächten, dorsalen Wirbelkörperperrandes beitragen können. Sie sollen deshalb einen Abstand von der dorsalen Kante der Deckplatte von mindestens 20 %, vorzugsweise mehr als 30 %, der größten in AP-Richtung gemessenen Abmessung der Deckplatte einhalten. Wenn die Zähne selbstschneidend und flächig ausgeführt sind, d.h. in der Art von Plättchen, deren Hauptebene quer zur Knochenoberfläche steht, kann es ferner zweckmäßig sein, wenn ihre Hauptebene in Sagittalrichtung verläuft. Das gilt insbesondere für diejenigen Zähne, die dem dorsalen Rand der Deckplatte nahe angeordnet sind. Dadurch wird erreicht, daß sie beim Einschieben der Prothesen in den Intervertebralraum nur geringe Kräfte nach dorsal auf den Knochen ausüben und dadurch dessen möglicherweise geschwächte Bereiche schonen. Schließlich kann es zweckmäßig sein, die dem dorsalen Rand nahen Zähne im Vergleich mit den weiter ventral angeordneten Zähnen zu kürzen, beispielsweise auf die halbe Höhe. Es kann in manchen Fällen genügen, diese Maßnahme auf einen oder wenige der dorsal angeordneten Zähne zu beschränken, beispielsweise auf den mittleren Zahn innerhalb einer Gruppe von drei dorsalen Zähnen, der gegebenenfalls auch fortgelassen werden kann, so daß sich dorsal nur zwei Verankerungszähne befinden.

Soweit es sich um typische, häufig in gleicher Form auftretende Schadensbilder handelt, können standardisierte Deckplatten vorgesehen sein, die unterschiedliche Größen oder Formen der Auswölbung, Abschrägung oder Abrundung tragen. Da es aber häufig erforderlich sein wird, der jeweils besonderen Form und Lage der Knochenmulden gerecht zu werden, zieht die Erfindung es vor, zumindest die Auswölbung, gewünschtenfalls aber auch die Abschrägung oder Abrundung, als besonderen Ansatzteil auszubilden, der mit einer geeigneten Deckplatte

verbunden werden kann. Es ist dann möglich, eine größere Anzahl verschiedener Ansatzteile vorzusehen. Unter diesen kann der jeweils passende ausgewählt und ggf. auch in unterschiedlicher, wählbarer Stellung mit der Deckplatte verbunden werden. Eine Kollektion von erfindungsgemäßen Wirbelprothesen kann daher eine Mehrzahl von verschiedenen Ansatzteilen sowie mindestens eine, vorzugsweise aber mehrere verschiedene, damit verbindbare Deckplatten vorsehen. Ggf. genügt auch eine Deckplatte mit variabler Anbringungsmöglichkeit für die Ansatzteile.

Ein Satz von Zwischenwirbelprothesen gemäß der Erfindung zeichnet sich dadurch aus, daß er mindestens eine Zwischenwirbelprothese umfaßt, deren Deckplattenoberfläche eine Vorwölbung aufweist, die stärker vorragt als die Deckplattenoberfläche bei den übrigen, normalen Prothesen.

Die Erfindung wird im folgenden näher unter Bezugnahme auf die Zeichnung erläutert, die vorteilhafte Ausführungsbeispiele veranschaulicht. Es zeigen:

Fig. 1 einen Sagittalschnitt durch einen Wirbelsäulenabschnitt,

Fig. 2 die Verhältnisse beim Einbringen einer herkömmlichen Prothese zwischen einem Wirbelkörperpaar,

Fig. 3 - 5 die entsprechende Konfiguration mit erfindungsgemäß geformten Prothesen,

Fig. 6 die Draufsicht auf eine Deckplattenoberfläche und deren Zahnanordnung und

Fig. 7 die Seitenansicht einer Deckplatte mit modularem Wölbungsansatz.

Das Wirbelkörperpaar 1, 2 umfaßt eine Bandscheibe 3 zwischen seinen einander zugewendeten Deckplatten. Der obere Wirbelkörper 1 enthält nahe seinem dorsalen Rand in der Oberfläche seiner unteren Deckplatte eine Mulde 4. Dabei kann es sich um eine Degenerationserscheinung oder eine natürliche Bildung handeln. Hinter der Mulde 4 verbleibt ein Knochenrand 5, der wegen des Fehlens von Knochenmaterial auf seiner der Mulde zugewendeten Seite nicht gut abgestützt ist und daher bruchempfindlich ist.

Wird gemäß Figur 2 eine herkömmliche Zwischenwirbelprothese 6 in den Raum zwischen den auseinandergespreizten Wirbelkörpern 1 und 2 in Pfeilrichtung eingeschoben, so kann es geschehen, daß die scharfe dorsale Kante 7 der Prothesendeckplatte gegen den empfindlichen Knochenrand 5 stößt und diesen nach dorsal ganz oder teilweise wegbricht.

Dies geschieht weniger leicht bei der in Figur 3 dargestellten ersten Ausführungsform einer erfindungsgemäßen Prothese. Die Deckplatte 11 ist nahe ihrem dorsalen Rand mit einer Auswölbung 12 versehen, die so ausgewählt wurde, daß sie etwa der Form der Mulde 4 entspricht. Ihre Oberfläche kann der Form eines Abschnitts eines Zylinders mit vorzugsweise in lateral-medialer Richtung liegender Achse oder einer Kugel oder eines Ellipsoids angenähert sein. Ihr dorsaler Rand 13 ist im Gegensatz zu dem herkömmlichen Ausführungsbeispiel in Figur 2 nicht kantig scharf, sondern abgeschrägt oder abgerundet ausgebildet. Die Abschrägung oder Abrundung geht monoton (d.h. ohne wesentliche Richtungsänderung) in die Oberfläche der Auswölbung 12 über. Auch wenn die Prothese beim Einführen schräg nach hinten oben zum Wirbelkörper 1 hin gerichtet sein

sollte, so daß die Deckplatte 11 an der Oberfläche des Wirbelkörpers entlanggleitet, besteht keine Gefahr, daß der vorgehende, dorsale Rand 13 der Deckplatte 11 am Knochenrand 5 ankantet. Er wird vielmehr sanft daran entlanggleiten, ohne eine gefährliche Kraft darauf auszuüben. Ebenso ist im eingebauten Zustand durch die Abschrägung oder Abrundung 13 dafür gesorgt, daß im Bereich des Knochenrands 5 keine übermäßigen Kräfte übertragen werden. Vielmehr stützt sich die Deckplatte 11 dank ihrer Auswölbung 12 in der Tiefe der Mulde 4 ab.

Figur 4 zeigt ein Beispiel, bei welchem die Deckplatte 14 der Prothese 15 keine Auswölbung aufweist, sondern lediglich eine Abschrägung 16 an ihrem dorsalen Rand. Während des Einsetzens sorgt die Abschrägung dafür, daß die hintere Kante der Deckplatte 14 sanft an den Knochenrand 5 entlanggleitet, wenn sie ihn überhaupt berührt. Figur 5 zeigt, daß im montierten Zustand die Abschrägung 16 den unmittelbaren Kontakt der Deckplatte 14 mit dem Knochenrand 5 vermeidet und dadurch dessen Gefährdung ausschließt. Statt dessen kann man die Deckplatte, deren normale dorsale Begrenzung in Fig. 6 durch die Linie 24 angegeben ist, auch dorsal gemäß der Linie 25 kürzen oder begradigen. Diese Ausführungsform der Erfindung erkennt man im Vergleich mit denjenigen Prothesen gleicher Größenstufe, die für normale Anwendungsfälle vorgesehen sind. Es kann erforderlich werden, für die nach dorsal gekürzten Deckplatten kleinere Prothesenkerne vorzusehen.

Figur 4 und 5 zeigen, daß die Deckplatten der Prothese 15 mit Zähnen 17, 18 versehen sind, die die Form von dreieckigen Plättchen haben, deren Ebene lotrecht zur Deck Plattenebene steht. Sie sind so scharf ausgebildet, daß sie sich selbstschneidend in die Knochenoberfläche einsenken, wenn die

Spreizung der Wirbelkörper nach dem Einführen der Prothese rückgängig gemacht wird. Es ist bekannt, derartige Zähne randparallel anzuordnen (EP-A-1057462). Für die Zähne 18, die entlang des ventralen Randes der Deckplatte 14 angeordnet sind, trifft dies auch für das vorliegende Ausführungsbeispiel zu. Die näher dem dorsalen Rand 16 angeordneten Zähne 17 sind jedoch erstens in großem Abstand von diesem Rand angeordnet und zweitens in AP-Richtung ausgerichtet, so daß sie weder beim Einschieben in einen engen Wirbelzwischenraum noch beim Einsenken in die Knochenoberfläche noch später während der normalen Funktion der Prothese eine schädliche, nach dorsal gerichtete Kraft auf den Knochen ausüben können. Überdies kann ihre Höhe geringer als die der Zähne 18 sein. Diese Maßnahmen können gemeinsam oder unabhängig voneinander angewendet werden.

Figur 7 veranschaulicht die Möglichkeit, eine Deckplatte 19 mit unterschiedlich geformten Vorwölbungen 20 zu versehen. Zu diesem Zweck sind zusammenwirkende Befestigungsmittel vorgesehen, die im einfachsten Fall aus Schrauben oder Stiften bestehen können. Im dargestellten Beispiel umfassen sie schwalbenschwanzförmige Leisten bzw. Nuten 21.

Die Prothesendeckplatten sind für eine feste Verbindung mit den Wirbelkörperdeckplatten vorgesehen. Dafür können geeignete Verbindungsmittel vorgesehen sein. Beispielsweise sind die Deckplatten 6, 11, 14 mit ventralen Flanschen 22 ausgerüstet, die in bekannter Weise zur Schraubbefestigung am Knochen herangezogen werden können und im übrigen ein zu weites Eindringen in den Zwischenwirbelraum verhüten. Ein anderes Beispiel für die Verankerung der Prothese am Knochen ist eine das Kno-

chenwachstum und die gegenseitige Verbindung fördernde biologische Beschichtung.

5 Auf die Erläuterung des Prothesenkerns wurde verzichtet, da dieser in unterschiedlichen Formen bekannt ist, die auch im Zusammenhang mit der Erfindung benutzt werden können.

10 Was als Vorwölbung einer Deckplatte und was als normale Deckplattenoberfläche zu betrachten ist, ist durch den Vergleich zwischen den normalen Prothesen und den mit einer Vorwölbung versehene Prothesen eines und desselben Prothesensatzes zu bestimmen. Meist sind die Deckplattenoberflächen, die sich am Wirbelkörper anlegen sollen, im wesentlichen eben gestaltet. In manchen Fällen weist die normale Deckplattenoberfläche eine geringfügige konvexe Wölbung auf, die der durchschnittlichen Krümmung der Wirbelkörperoberflächen komplementär
15 gleicht. Die Vorwölbung ist dann der konvexe Bereich der sich über eine entsprechend eben bzw. naturgemäß schwach gewölbt gedachte Oberfläche der Deckplatte erhebt. Als erfindungsgemäße Vorwölbung ist jedenfalls ein solcher Teil der Prothesendeckplatte zu betrachten, dessen Krümmungsradius in der
20 Sagittalebene geringer ist als 40 mm, vorzugsweise 30 mm oder der sich über den Kreisbogen 26 (siehe Fig. 7) erhebt, der im Sagittalschnitt durch die Kanten der Deckplatte verläuft und eine Bogenhöhe von 4 mm, vorzugsweise 3 mm über der geraden
25 Verbindungslinie dieser Kanten hat.

Patentansprüche

1. Zwischenwirbelprothese mit wenigstens einer in Anlage an einem Wirbelkörper (1, 2) mit diesem zu verbindenden
5 Deckplatte (11, 19), dadurch gekennzeichnet, daß die dem Wirbelkörper (1) zugewendete Deckplattenoberfläche eine über die Anpassung an die normal Wirbelkörperform hinausgehende Vorwölbung (12) aufweist.
- 10 2. Zwischen Wirbelprothese nach Anspruch 1, dadurch gekennzeichnet, daß die Vorwölbung (12) eine geringere Ausdehnung als die Deckplattenoberfläche aufweist.
- 15 3. Zwischenwirbelprothese nach Anspruch 2, dadurch gekennzeichnet, daß die Vorwölbung (12) dem dorsalen Rand (13) der Deckplattenoberfläche näher liegt als ihrem ventralen Rand.
- 20 4. Zwischenwirbelprothese nach Anspruch 3, dadurch gekennzeichnet, daß die Vorwölbung (12) bis an die dorsale Kante (13) der Deckplattenoberfläche heranreicht.
- 25 5. Zwischenwirbelprothese insbesondere nach Anspruch 4 mit wenigstens einer in Anlage an einem Wirbelkörper (1) mit diesem zu verbindenden Deckplatten (11, 14,), dadurch gekennzeichnet, daß am Rand der dem Wirbelkörper (1) zugewendeten Deckplattenoberfläche eine Abschrägung oder Abrundung (13, 16) vorgesehen ist.
- 30 6. Zwischenwirbelprothese nach Anspruch 5, dadurch gekennzeichnet, daß die Abschrägung oder Abrundung (13, 16) mindestens an der dorsalen Seite vorgesehen ist.

7. Zwischenwirbelprothese nach 5 oder 6, dadurch gekennzeichnet, daß die Abschrägung oder Abrundung (13, 16) sich über mindestens 5 % der Abmessung der Deckplattenoberfläche in AP-Richtung erstreckt.
- 5
8. Zwischenwirbelprothese nach einem der Ansprüche 5 bis 7, dadurch gekennzeichnet, daß die Abschrägung oder Abrundung (13) Teil einer Vorwölbung (12) gemäß Anspruch 4 ist.
- 10
9. Zwischenwirbelprothese insbesondere nach einem der Ansprüche 1 bis 8, mit wenigsten einer in Anlage an einem Wirbelkörper (1) mit diesem zu verbindenden Deckplatte (14), die in den Wirbelkörper (1) einzudringen bestimmte Zähne (17) aufweist, dadurch gekennzeichnet, daß der Abstand der Zähne (17) von der dorsalen Kante der Deckplatte (14) mindestens 20 % der Deckplattenabmessung in AP-Richtung beträgt.
- 15
10. Zwischenwirbelprothese nach Anspruch 9, dadurch gekennzeichnet, daß wenigstens einer der nahe der dorsalen Kante angeordneten, selbstschneidend ausgebildeten Zähne (17) im wesentlichen in Sagittalrichtung verläuft.
- 20
11. Zwischenwirbelprothese nach Anspruch 9, dadurch gekennzeichnet, daß wenigstens einer der nahe der dorsalen Kante angeordneten Zähne eine geringere Höhe als weiter ventral angeordnete Zähne hat.
- 25
12. Zwischenwirbelprothese nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß die Vorwölbung (12) oder Abschrägung oder Abrundung (13, 16) von einem mit der Deck-
- 30

platte (19) verbundenen bzw. zu verbindenden, gesonderten Ansatzteil (20) gebildet ist.

5 13. Zwischenwirbelprothese nach Anspruch 12, dadurch gekennzeichnet, daß eine Mehrzahl von verschiedenen Ansatzteilen (20) und einer geringe Anzahl von damit verbindbaren, verschiedenen Deckplatten (19) vorgesehen ist.

10 14. Satz von Zwischenwirbelprothesen, die wenigstens eine in Anlage an einem Wirbelkörper (1) mit diesem zu verbindende Deckplatte (11, 19) mit einer im wesentlichen flachen Deckplattenoberfläche aufweisen, dadurch gekennzeichnet, daß er mindestens eine Zwischenwirbelprothese umfaßt, deren Deckplattenoberfläche eine Vorwölbung (20) aufweist.

15

15. Satz von Zwischenwirbelprothesen, die wenigstens eine in Anlage an einem Wirbelkörper (1) mit diesem zu verbindende Deckplatte (11, 19) mit einem dorsalen Rand aufweisen, dadurch gekennzeichnet, daß er mindestens eine Zwischenwirbelprothese umfaßt, an deren Deckplatte der dorsale Rand gekürzt ist.

20

Fig. 1

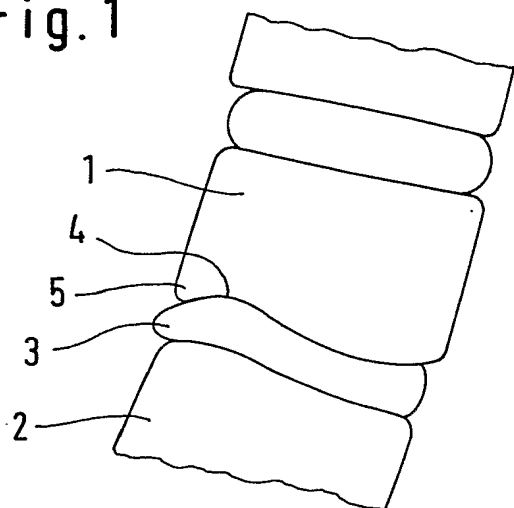


Fig. 2

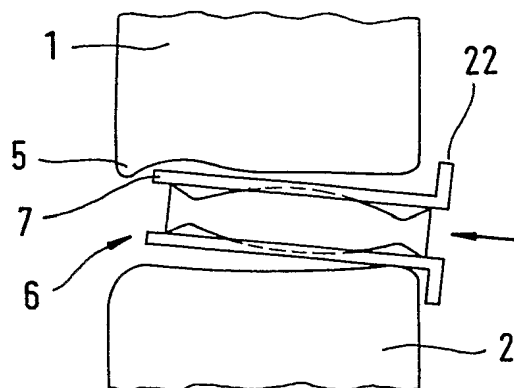


Fig. 3

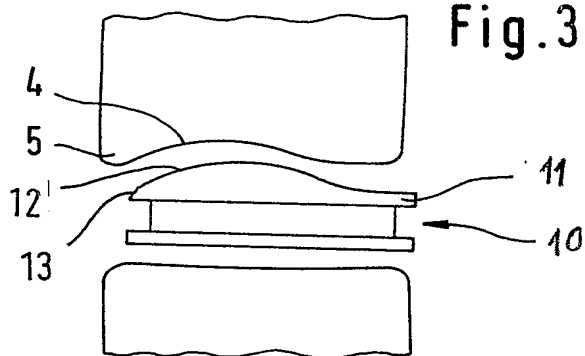


Fig. 5

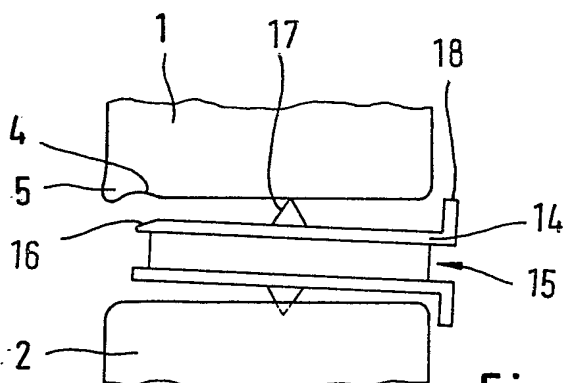
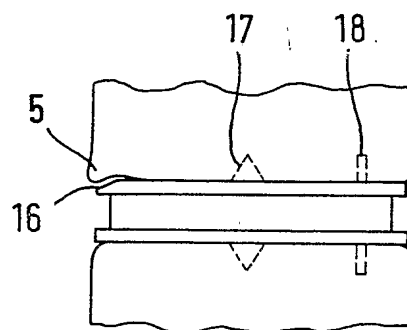


Fig. 4

Fig. 6

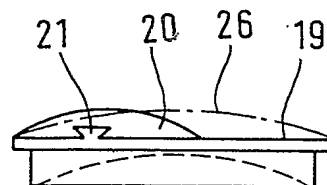
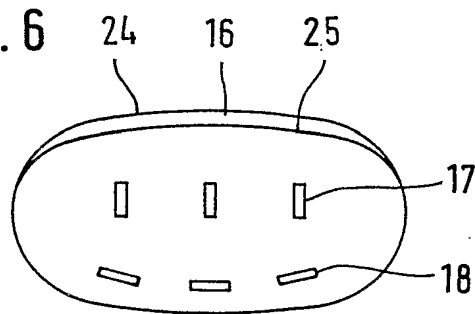


Fig. 7

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/EP 03/00372

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 13619 A (BRYAN VINCENT ; SPINAL DYNAMICS CORP (US)) 16 March 2000 (2000-03-16) figures 1,3,4 page 3, line 30 - line 31 ---	1,2,4
X	US 5 306 308 A (KADEN BERTRAM ET AL) 26 April 1994 (1994-04-26) figures 1,3,4B claim 2 ---	1-3
X	US 5 514 180 A (HEGGENESS MICHAEL H ET AL) 7 May 1996 (1996-05-07) figure 18A column 9, line 23 - line 38 ---	1,2
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 March 2003

Date of mailing of the international search report

16/04/2003

Name and mailing address of the ISA

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Authorized officer

Josten, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/00372

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 6 395 034 B1 (SUDDABY LOUBERT) 28 May 2002 (2002-05-28) figure 7B column 2, line 39 - line 42 column 4, line 4 - line 7 -----</p>	1-4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 03/00372

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 5-15
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
SEE SUPPLEMENTAL BOX, ADDITIONAL MATTER PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Continuation of Box I.2

Claims No.: 5-15

The present application contains the independent claims 1, 5, 9, 14 and 15. It is pointed out that the reference in claims 5 and 9 to one or more of the preceding claims is optional, owing to the use of the expression "in particular", and that the claims 5 and 9 are therefore also considered independent claims.

In view of the large number of independent claims, it is difficult, if not impossible, to determine the range of protection sought in these claims. For this reason, the present application does not meet the requirements of PCT Article 6 (conciseness of the claims) to such an extent that a meaningful search cannot be conducted. The search was therefore directed to the parts of the claims which appear to meet the conciseness requirement in the above sense, namely claims 1 to 4.

The applicant is advised that claims or parts of claims relating to inventions in respect of which no international search report has been established cannot normally be the subject of an international preliminary examination (PCT Rule 66.1(e)). In its capacity as International Preliminary Examining Authority the EPO generally will not carry out a preliminary examination for subjects that have not been searched. This also applies to cases where the claims were amended after receipt of the international search report (PCT Article 19) or where the applicant submits new claims in the course of the procedure under PCT Chapter II.

INTERNATIONAL SEARCH REPORT

Int. Patent Application No
PCT/EP 03/00372

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0013619	A	16-03-2000	AU 754516 B2	21-11-2002
			AU 5705799 A	27-03-2000
			CA 2342633 A1	16-03-2000
			EP 1109516 A1	27-06-2001
			JP 2002524141 T	06-08-2002
			WO 0013619 A1	16-03-2000
<hr/>				
US 5306308	A	26-04-1994	DE 8912648 U1	22-11-1990
			WO 9105521 A1	02-05-1991
			DE 59003981 D1	03-02-1994
			EP 0497803 A1	12-08-1992
<hr/>				
US 5514180	A	07-05-1996	NONE	
<hr/>				
US 6395034	B1	28-05-2002	NONE	
<hr/>				

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 03/00372

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 00 13619 A (BRYAN VINCENT ; SPINAL DYNAMICS CORP (US)) 16. März 2000 (2000-03-16) Abbildungen 1,3,4 Seite 3, Zeile 30 - Zeile 31 ---	1,2,4
X	US 5 306 308 A (KADEN BERTRAM ET AL) 26. April 1994 (1994-04-26) Abbildungen 1,3,4B Anspruch 2 ---	1-3
X	US 5 514 180 A (HEGGENESS MICHAEL H ET AL) 7. Mai 1996 (1996-05-07) Abbildung 18A Spalte 9, Zeile 23 - Zeile 38 --- -/--	1,2



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :

- *A* Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
- *E* älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
- *L* Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
- *O* Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
- *P* Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist

T Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist

X Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden

Y Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist

G Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche

20. März 2003

Absendedatum des internationalen Recherchenberichts

16/04/2003

Name und Postanschrift der Internationalen Recherchenbehörde

Europäisches Patentamt, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Bevollmächtigter Bediensteter

Josten, S

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 03/00372

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	<p>US 6 395 034 B1 (SUDDABY LOUBERT) 28. Mai 2002 (2002-05-28) Abbildung 7B Spalte 2, Zeile 39 - Zeile 42 Spalte 4, Zeile 4 - Zeile 7 -----</p>	1-4

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP 03/00372

Feld I Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein Recherchenbericht erstellt:

1. ☐ Ansprüche Nr.
weil sie sich auf Gegenstände beziehen, zu deren Recherche die Behörde nicht verpflichtet ist, nämlich
2. ☒ Ansprüche Nr. 5-15
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, daß eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich
siehe Zusatzblatt WEITERE ANGABEN PCT/ISA/210
3. ☐ Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefaßt sind.

Feld II Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)

Die internationale Recherchenbehörde hat festgestellt, daß diese internationale Anmeldung mehrere Erfindungen enthält:

1. ☐ Da der Anmelder alle erforderlichen zusätzlichen Recherchegebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.
2. ☐ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der eine zusätzliche Recherchegebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung einer solchen Gebühr aufgefordert.
3. ☐ Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchegebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.
4. ☐ Der Anmelder hat die erforderlichen zusätzlichen Recherchegebühren nicht rechtzeitig entrichtet. Der internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfaßt:

Bemerkungen hinsichtlich eines Widerspruchs

- ☐ Die zusätzlichen Gebühren wurden vom Anmelder unter Widerspruch gezahlt.
- ☐ Die Zahlung zusätzlicher Recherchegebühren erfolgte ohne Widerspruch.

WEITERE ANGABEN

PCT/ISA/ 210

Fortsetzung von Feld I.2

Ansprüche Nr.: 5-15

Die vorliegende Anmeldung enthält die unabhängigen Ansprüche 1, 5, 9, 14 und 15. Es wird darauf hingewiesen, dass in den Ansprüchen 5 und 9 der Rückbezug auf einen oder mehrere vorangehende Ansprüche aufgrund der Verwendung des Wortes "insbesondere" fakultativ ist und diese Ansprüche 5 und 9 somit ebenfalls als unabhängige Ansprüche gelten.

Angesichts dieser großen Zahl an unabhängigen Ansprüchen ist es erschwert, wenn nicht gar unmöglich gemacht, den durch sie erstrebten Schutzzumfang zu bestimmen. Die vorliegende Patentanmeldung entspricht deshalb den Anforderungen des Artikels 6 PCT (Knappheit der Ansprüche) in einem Maße nicht, daß eine sinnvolle Recherche undurchführbar ist. Daher wurde die Recherche auf die Teile der Patentansprüche gerichtet, welche im o.a. Sinne dem Erfordernis der Knappheit genügen, nämlich auf die Ansprüche 1 bis 4.

Der Anmelder wird darauf hingewiesen, daß Patentansprüche, oder Teile von Patentansprüchen, auf Erfindungen, für die kein internationaler Recherchenbericht erstellt wurde, normalerweise nicht Gegenstand einer internationalen vorläufigen Prüfung sein können (Regel 66.1(e) PCT). In seiner Eigenschaft als mit der internationalen vorläufigen Prüfung beauftragte Behörde wird das EPA also in der Regel keine vorläufige Prüfung für Gegenstände durchführen, zu denen keine Recherche vorliegt. Dies gilt auch für den Fall, daß die Patentansprüche nach Erhalt des internationalen Recherchenberichtes geändert wurden (Art. 19 PCT), oder für den Fall, daß der Anmelder im Zuge des Verfahrens gemäß Kapitel II PCT neue Patentansprüche vorlegt.

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 03/00372

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
WO 0013619	A	16-03-2000	AU	754516 B2	21-11-2002
			AU	5705799 A	27-03-2000
			CA	2342633 A1	16-03-2000
			EP	1109516 A1	27-06-2001
			JP	2002524141 T	06-08-2002
			WO	0013619 A1	16-03-2000
US 5306308	A	26-04-1994	DE	8912648 U1	22-11-1990
			WO	9105521 A1	02-05-1991
			DE	59003981 D1	03-02-1994
			EP	0497803 A1	12-08-1992
US 5514180	A	07-05-1996	KEINE		
US 6395034	B1	28-05-2002	KEINE		

(19) World Intellectual Property
Organization
International Bureau



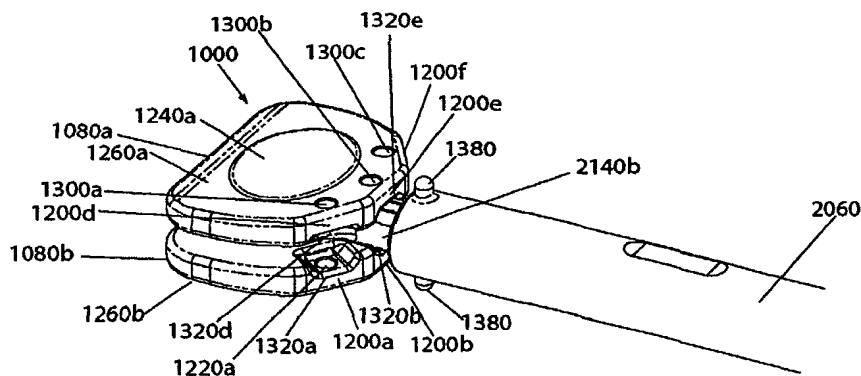
(43) International Publication Date
13 May 2004 (13.05.2004)

PCT

(10) International Publication Number
WO 2004/039291 A1

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(54) Title: INSTRUMENTATION, METHODS, AND FEATURES FOR USE IN IMPLANTING AN ARTIFICIAL INTERVERTEBRAL DISC



(57) Abstract: Instrumentation for implanting an artificial intervertebral disc includes static trials and a dynamic trial for determining the appropriate size of disc to be implanted, static trial holders (2060) for manipulating the static trials (1000), inserter/impactors for inserting and removing the static trials and for inserting the artificial intervertebral discs, repositioners/extractors for repositioning and extracting the static trials or the artificial intervertebral discs, and a leveler for setting the proper position of the artificial intervertebral disc. Methods for using the same are also disclosed. Features for artificial intervertebral discs and intervertebral spacer devices useful for manipulation by the instrumentation are also disclosed.

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**INSTRUMENTATION, METHODS, AND FEATURES FOR USE IN
IMPLANTING AN ARTIFICIAL INTERVERTEBRAL DISC**

CROSS-REFERENCE TO RELATED APPLICATIONS

5 [0001] The present application is a continuing application of U.S. Patent Application
Serial Number ("USPASN") 10/282,356 (filed October 29, 2002) entitled "Instrumentation and
Methods for use in Implanting an Artificial Intervertebral Disc" ("the '356 application") and a
continuing application of USPASN 10/309,585 (filed December 4, 2002) entitled "Static Trials
and Related Instruments and Methods for use in Implanting an Artificial Intervertebral Disc" ("the
10 '585 application") and a continuing application of USPASN 10/425,267 (filed April 29, 2003)
entitled "Wedge Plate Inserter/Impactor and Related Methods for use in Implanting an Artificial
Intervertebral Disc" ("the '267 application"). The '356 application is a continuing application of
USPASN 10/256,160 (filed September 26, 2002) entitled "Artificial Intervertebral Disc Having
Limited Rotation Using a Captured Ball and Socket Joint With a Solid Ball and Compression
15 Locking Post" ("the '160 application"), which is a parent application of USPASN 10/642,528 (filed
August 15, 2003) entitled "Axially Compressible Artificial Intervertebral Disc Having Limited
Rotation Using a Captured Ball and Socket Joint With a Solid Ball and Compression Locking
Post" ("the '528 application") and a continuing application of USPASN 10/175,417 (filed June 19,
2002) entitled "Artificial Intervertebral Disc Utilizing a Ball Joint Coupling", which is a continuing
20 application of USPASN 10/151,280 (filed May 20, 2002) entitled "Tension Bearing Artificial Disc
Providing a Centroid of Motion Centrally Located Within an Intervertebral Space", which is a
continuing application of both USPASN 09/970,479 (filed October 4, 2001) entitled
"Intervertebral Spacer Device Utilizing a Spirally Slotted Belleville Washer Having Radially
Extending Grooves" as well as USPASN 10/140,153 (filed May 7, 2002) entitled "Artificial
25 Intervertebral Disc Having a Flexible Wire Mesh Vertebral Body Contact Element", the former
being a continuing application of USPASN 09/968,046 (filed October 1, 2001) entitled
"Intervertebral Spacer Device Utilizing a Belleville Washer Having Radially Extending Grooves"
and the latter being a continuing application of both USPASN 09/970,479 (detailed above) as
well as USPASN 10/128,619 (filed April 23, 2002) entitled "Intervertebral Spacer Having a
30 Flexible Wire Mesh Vertebral Body Contact Element", which is a continuing application of both
USPASN 09/906,119 (filed July 16, 2001) and entitled "Trial Intervertebral Distraction Spacers"
as well as USPASN 09/982,148 (filed October 18, 2001) and entitled "Intervertebral Spacer

Device Having Arch Shaped Spring Elements". All of the above mentioned applications are hereby incorporated by reference herein in their respective entireties.

FIELD OF THE INVENTION

[0002] This invention relates generally to systems and methods for use in spine
5 arthroplasty, and more specifically to instruments for distracting an intervertebral space, inserting and removing trial artificial intervertebral discs, and inserting, impacting, repositioning, leveling and extracting artificial intervertebral discs, and methods of use thereof, and also more specifically to intervertebral spacer devices and artificial intervertebral discs having features rendering them suitable for manipulation thereby.

BACKGROUND OF THE INVENTION

[0003] The bones and connective tissue of an adult human spinal column consists of more than twenty discrete bones coupled sequentially to one another by a tri-joint complex that consists of an anterior disc and the two posterior facet joints, the anterior discs of adjacent
10 bones being cushioned by cartilage spacers referred to as intervertebral discs. These more than twenty bones are anatomically categorized as being members of one of four classifications: cervical, thoracic, lumbar, or sacral. The cervical portion of the spine, which comprises the top of the spine, up to the base of the skull, includes the first seven vertebrae. The intermediate twelve
15 bones are the thoracic vertebrae, and connect to the lower spine comprising the five lumbar vertebrae. The base of the spine is the sacral bones (including the coccyx). The component bones of the cervical spine are generally smaller than those of the thoracic spine, which are in turn smaller than those of the lumbar region. The sacral region connects laterally to the pelvis. While the sacral region is an integral part of the spine, for the purposes of fusion surgeries and for this disclosure, the word spine shall refer only to the cervical, thoracic, and lumbar regions.

[0004] The spinal column is highly complex in that it includes these more than twenty
20 bones coupled to one another, housing and protecting critical elements of the nervous system having innumerable peripheral nerves and circulatory bodies in close proximity. In spite of these complications, the spine is a highly flexible structure, capable of a high degree of curvature and twist in nearly every direction.

[0005] Genetic or developmental irregularities, trauma, chronic stress, tumors, and
25 degenerative wear are a few of the causes that can result in spinal pathologies for which surgical intervention may be necessary. With respect to the failure of the intervertebral disc, and the insertion of implants and/or height restorative devices, several methods and devices have

been disclosed in the prior art that achieve immobilization and/or fusion of adjacent bones by implanting artificial assemblies in or on the spinal column. More recently, the development of non-fusion implant devices, which purport to permit continued natural movement in the tri-joint complex, have provided great promise as a preferably alternative to fusion devices. The region of the back that needs to be corrected, as well as the individual variations in anatomy, determine the appropriate surgical protocol and implantation assembly. Generally, the preparation of the intervertebral space for the receipt of fusion or non-fusion devices involves removing the damaged disc material and thereafter distracting the adjacent vertebral bones to their appropriate distance apart. Once the proper height of the intervertebral space is restored, the fusion or non-fusion device can be implanted.

[0006] It is an object of the invention to provide artificial intervertebral disc and intervertebral spacer device features, as well as instrumentation and methods, that enable surgeons to more accurately, easily, and efficiently prepare the intervertebral space and implant fusion or non-fusion devices. Other objects of the invention not explicitly stated will be set forth and will be more clearly understood in conjunction with the descriptions of the preferred embodiments disclosed hereafter.

SUMMARY OF THE INVENTION

[0007] The preceding objects are achieved by the invention, which includes artificial intervertebral disc and intervertebral spacer device features suitable for manipulation thereof by surgical instrumentation, and further includes static trial artificial intervertebral discs (sometimes referred to herein as a "static trial"), static trial artificial intervertebral disc holders (sometimes referred to herein as "static trial holders"), a dynamic trial artificial intervertebral disc (sometimes referred to herein as a "dynamic trial"), artificial intervertebral disc inserter/impactors (sometimes referred to herein as "inserter/impactors"), an artificial intervertebral disc repositioner/extractor (sometimes referred to herein as a "repositioner/extractor"), and an artificial intervertebral disc leveler (sometimes referred to herein as a "leveler").

[0008] More particularly, the features, systems, and methods disclosed herein are intended for use in spine arthroplasty procedures, and specifically for use with the features, systems, and methods described herein in conjunction with the features, systems, and methods described in the '356, '585, '267, '160, and '528 applications, as well as those described in USPASN 09/906,127 (filed July 16, 2001) entitled "Insertion Tool For Use With Intervertebral Spacers" ("the '127 application"), which is hereby incorporated by reference herein. However, it

should be understood that the features, systems, and methods described herein are also suitable for use with other features, systems, and methods without departing from the scope of the invention.

[0009] For example, while the static trials described herein are primarily intended for use in determining the appropriate size of particular embodiments of the artificial intervertebral disc implants described in the '160 and '528 applications to be implanted (or whether a particular size can be implanted) into the distracted intervertebral space, they can also be used for determining the appropriate size of any other suitably configured orthopedic implant or trial to be implanted (or whether a particular size can be implanted) into the distracted intervertebral space. They can also be used to distract an intervertebral space (e.g., in the same manner in which the trial spacers in the '127 application are used as described in the '127 application).

[0010] And, for example, while the static trial holders described herein are primarily intended for use in holding, inserting, removing, and otherwise manipulating the static trials described herein, they can also be used for manipulating any embodiment of the trial spacers described in the '127 application (also referred to therein and herein as distraction spacers), and can also be used for manipulating any other suitably configured orthopedic device.

[0011] And, for example, while the dynamic trial described herein is primarily intended for use in distracting an intervertebral space according to the procedures described herein and/or for determining the appropriate size of particular embodiments artificial intervertebral disc implants described in the '160 and '528 applications to be implanted (or whether a particular size can be implanted) into the distracted intervertebral space, it can also be used for distracting an intervertebral space according to other procedures and/or for determining the appropriate size of any other suitably configured orthopedic implant or trial to be implanted (or whether a particular size can be implanted) into the distracted intervertebral space.

[0012] And, for example, while the inserter/impactors described herein are primarily intended for use in holding, inserting, removing, impacting, extracting, and otherwise manipulating particular embodiments of the artificial intervertebral disc implants described in the '160 and '528 applications, they can also be used for manipulating any other suitably configured orthopedic implant or trial.

[0013] And, for example, while the repositioners/extractors described herein are primarily intended for use in repositioning and/or extracting and/or otherwise manipulating particular embodiments of the artificial intervertebral disc implants described in the '160 and '528

applications, they can also be used for manipulating any other suitably configured orthopedic implant or trial.

[0014] And, for example, while the leveler described herein is primarily intended for use in setting the proper position of, and/or otherwise manipulating, particular embodiments of the artificial intervertebral disc implants described in the '160 and '528 applications, it can also be used for manipulating any other suitably configured orthopedic implant or trial.

[0015] While the instrumentation described herein (e.g., the static trials, static trial holders, dynamic trial, inserter/impactors, repositioners/extractors, and leveler) will be discussed for use with the artificial intervertebral disc of Figs. 1g-n, such discussions are merely by way of example and not intended to be limiting of their uses. Thus, it should be understood that the tools can be used with any of the artificial intervertebral discs disclosed in the '160 and '528 applications, or any other artificial intervertebral disc having (or being modifiable or modified to have) suitable features therefor. Moreover, it is anticipated that the features of the artificial intervertebral disc (e.g., the angled flat surfaces and accompanying holes and inwardly facing baseplate surfaces) and/or the static trials (e.g., the cylindrical trunks and angled flat surfaces and opposing notches and accompanying holes) that are used by the tools discussed herein to hold and/or manipulate these devices (such features, it should be noted, were first shown and disclosed in the '356, '585, '267, '160, and/or '528 applications) can be applied, individually or collectively or in various combinations, to other trials, spacers, artificial intervertebral discs or other orthopedic devices as stand-alone innovative features for enabling such trials, spacers, artificial intervertebral discs, or other orthopedic devices to be more efficiently and more effectively held and/or manipulated by the tools described herein or by other tools having suitable features. In addition, it should be understood that the invention encompasses artificial intervertebral discs, spacers, trials (static or dynamic), and/or other orthopedic devices, that have one or more of the features disclosed herein, in any combination, and that the invention is therefore not limited to artificial intervertebral discs, spacers, trials, and/or other orthopedic devices having all of the features simultaneously.

[0016] More particularly with regard to the static trials described herein, a plurality of static trials are provided primarily for use in determining the appropriate size of an artificial intervertebral disc to be implanted (or whether a particular size of the artificial intervertebral disc can be implanted) into the distracted intervertebral space (e.g., the artificial intervertebral disc 160 of Figs. 1g-n). Preferably, for each artificial intervertebral disc to be implanted, a plurality of sizes of the artificial intervertebral disc would be available. That is, preferably, a plurality of the

same type of artificial intervertebral disc would be available, each of the plurality having a respective width and depth dimension combination that allows it to fit within a correspondingly dimensioned intervertebral space. For example, the plurality of artificial intervertebral discs could include artificial intervertebral discs having widths being either 35mm or 40mm, and
5 depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 discs. Accordingly, preferably, each of the plurality of static trials for use with a particular plurality of differently sized artificial intervertebral discs would have a respective width and depth dimension set corresponding to the width and depth of a respective one of the plurality of differently sized artificial intervertebral discs. For example, the plurality of static trials for use with the set of
10 artificial intervertebral discs described for example could include static trials having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 static trials. It should be understood that the artificial intervertebral discs and/or the static trials can be offered in a variety of dimensions without departing from the scope of the invention, and that the dimensions specifically identified and quantified herein are merely exemplary.

15 Moreover, it should be understood that the set of static trials need not include the same number of trials for each artificial intervertebral disc in the set of artificial intervertebral discs, but rather, none, one, or more than one trial can be included in the trial set for any particular artificial intervertebral disc in the set.

[0017] Each of the plurality of static trials preferably further includes features that can be
20 used by the static trial holders (described below), the inserter/impactors (described below), and the repositioners/extractors (described below). With regard to a feature that can be used by the static trial holder, each static trial preferably includes a recess that can be engaged by the opposing semicircular extents of the static trial holder. Preferably, this recess forms a perimetrical groove (a groove that extends around at least a portion of the perimeter of the static
25 trial, e.g., an annular groove) that establishes a trunk (e.g., a cylindrical trunk) between the baseplates of the static trial, such that the baseplates extend as flanges from either end of the trunk. Accordingly, preferably, the opposing semicircular extents each have a thickness smaller than the width of the annular groove, and as such fit into the annular groove to grip the cylindrical trunk between them.

30 [0018] Additional features that can be used by the static trial holders include (on any static trial surface that faces the desired engagement approach direction of the static trial holder, e.g., on each of the anteriorly facing and anterior-laterally facing flat surfaces of the static trial as described below) opposing recesses, preferably formed as upper and lower notches, an upper

notch in the upper baseplates and a lower notch in the lower baseplate. Preferably, the notches are sized so that the opposing notches of each pair form a volume that is dimensioned to closely accommodate the dimensions of the static trial holder's prongs' cross-section. That is, as described below, the body of each prong is thicker than the semicircular extent that extends from the body, and as such, whereas the semicircular extents fit into the annular groove, the prongs do not because their thickness is greater than the width of the annular groove opening. Each notch pair accommodates this greater thickness, and as such, as the opposing semicircular extents of the static trial holder are placed into the annular groove, the bodies of the prongs of the static trial holder pass into the notches so that the semicircular extents can continue into the annular groove and be seated around the cylindrical trunk. Once the prongs are fitted within the notch pair, interference between the prongs and the notch walls limits or prevents rotation of the static trial about a longitudinal axis (e.g., an axis parallel to the longitudinal axis of the cylindrical trunk) with respect to the static trial holder.

[0019] With regard to features that can be used by the inserter/impactors, each static trial (and each artificial intervertebral disc that the trials approximate) preferably includes an anteriorly facing flat surface, flanked by two anteriolaterally facing flat surfaces (one on each side of the anteriorly facing flat surface), and, to provide for holding of the static trial or disc for an anterior insertion approach, a hole spaced from the anteriorly facing flat surface, the hole having a longitudinal axis parallel to the anteriorly facing flat surface. The holding pin of the inserter/impactor fits within the hole, and the angled flat surfaces of the static trial or disc fit against the correspondingly angled flat surfaces of the inserter/impactor, and operation of the inserter/impactor pulls the holding pin toward the flat surface of the inserter/impactor opposite the pin, to rigidly hold the static trial or disc by the baseplate.

[0020] In some embodiments of the inserter/impactor having a wedge plate, the holding pin protrudes from a wedge-shaped extended surface of the distal end of the inserter/impactor and is restricted from upward movement with respect to the distal head by the presence of the wedge-shaped extended surface of the distal end of the inserter/impactor. More particularly, with any attempted upward movement of the holding pin, the pin encounters the upper surface of the channel in which the pin travels, preventing any such upward movement.) When the static trial or artificial disc is held in this manner, rotation of the static trial or disc about a longitudinal axis (e.g., in the case of the trials, an axis parallel to the longitudinal axis of the cylindrical trunk) relative to the inserter/impactor is prevented by interference of the corners of the static trial's or disc's flat surfaces and the corners of the inserter/impactor's flat surfaces, similar to the manner

in which a wrench holding a nut prevents rotation of the nut relative to the wrench. Further, the holding of the static trial or disc in this manner allows for some repositioning of the static trial or disc in the intervertebral space via rotation of the static trial or disc in either direction about the longitudinal axis of the intervertebral space.

5 [0021] Further, in some embodiments of the inserter/impactor having a wedge plate, when the trial or disc is held in this manner, rotation of the trial or disc about a lateral axis of the trial or disc relative to the inserter/impactor is prevented by interference of the inwardly facing surface of the first baseplate (e.g., upper baseplate) of the trial or disc and the corresponding surface (e.g., upper surface) of the wedge on the distal end, and by interference of the inwardly
10 facing surface of the second baseplate (e.g., lower baseplate) of the trial or disc and the corresponding surface (e.g., lower surface) of the wedge on the distal end. With regard to artificial discs, it is preferable that the wedge on the inserter/impactor will interfere between the first and second baseplates (e.g., upper and lower) so that the surfaces of the first and second baseplates align at a preferred 15 degrees angle of lordosis when the disc is held by the
15 inserter/impactor.

[0022] Preferably, both of the baseplates of the static trial or disc have similarly configured flat surfaces, and both baseplates' flat surfaces fit against the angled flat surfaces of the inserter/impactor to provide for a more secure holding of the static trial or disc by the inserter/impactor. Also preferably, in order to provide for a holding of the static trial or disc for
20 two additional (here, anteriolateral) insertion approaches, each static trial or disc also includes two additional holes, one spaced apart from one of the anteriolaterally facing flat surfaces, and the other spaced apart from the other of the anteriolaterally facing flat surfaces. Accordingly, operation of the inserter/impactor can fit the holding pin into either of these two additional holes, and hold the anteriolaterally facing flat surface (the one associated with the hole into which the
25 pin is fit) of the static trial or disc against the flat surface of the inserter/impactor opposite the pin. It should be understood that preferably, in order to facilitate these two additional approaches, the angle separating the anteriorly facing flat surface of the static trial or disc and one of the anteriolaterally facing flat surfaces of the static trial or disc is equal to the angle separating the anteriorly facing flat surface and the other of the anteriolaterally facing flat surfaces.

30 [0023] With regard to features that can be used by the repositioners/extractors, each static trial (and each artificial intervertebral disc that the trials approximate) preferably includes at least two holes extending longitudinally into one of the baseplates of the trial or disc from the inwardly facing surface of the baseplate. More than two holes can be used to provide for

multiple repositioning/extracting approaches. Preferably, in order for the same repositioning/extracting tool to be used for multiple approaches on the same trial or artificial intervertebral disc, adjacent holes should be separated by the same distance separating other adjacent holes.

5 [0024] As discussed in greater detail below with regard to the repositioners/extractors, in order to engage two of the holes, each repositioner/extractor has two pins extending in parallel from a central shaft, perpendicular to the longitudinal axis of the central shaft. The pins can be inserted into the holes, and pulling or pushing on the central shaft along its longitudinal axis when the holes are engaged pulls or pushes the static trial or artificial intervertebral disc in the
10 intervertebral space. Further, because two holes are engaged, the static trial or artificial intervertebral disc can be rotated in either direction about a longitudinal axis passing through the intervertebral space, by rotating of the central shaft of the repositioner/extractor about its distal end, about an axis parallel to the longitudinal axes of the pins.

 [0025] On each repositioner/extractor, the pins are formed on prongs that extend
15 laterally from the central shaft. The direction of the prongs, and the location of the pins relative to the central shaft, determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Further, the number and location of holes further determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Accordingly, the present invention contemplates a variety of repositioner/extractors, and a
20 variety of holes configurations, to provide the surgeon with a variety of possible surgical approach angles.

 [0026] As described in greater detail below, three repositioner/extractors are illustrated and described (symmetric, offset left, and offset right) for example,, and, for example, two hole configurations are illustrated and described. A first hole configuration includes the hole
25 configuration described above, that is, three holes on one of the baseplates (e.g., the lower baseplate), the holes being configured so that a first hole is located in the anterior-posterior plane, and the adjacent (second and third) holes are located in respective opposing anteriolateral planes on either side of the first hole. A second hole configuration includes four holes on one of the baseplates (e.g., the upper baseplate), the holes being configured so that
30 first and second holes straddle the anterior-posterior plane, a third hole is located so that the third hole and the first hole straddle one of the opposing anteriolateral planes, and a fourth hole is located so that the fourth hole and the second hole straddle the other of the opposing anteriolateral planes.

[0027] With regard to the static trial holders described herein, the static trial holders are provided primarily for use in holding, inserting, removing, and otherwise manipulating the static trials described herein. Preferably, the static trial holder has (in some embodiments, at an end of an extension of the static trial holder) a pair of opposing prongs that open away from one another and close toward one another. Each of the prongs has a semicircular extent and the semicircular extents face one another to define a circular holding enclosure that is useful for capturing the cylindrical trunk of the static trial between them. The prongs are spring biased toward a neutral position such that the holding enclosure is spring biased to a receptive state in which the cylindrical trunk can be snapped into (or out of) the holding enclosure by temporarily placing the holding enclosure in an expanded state (by forcing the cylindrical trunk against the mouth of the enclosure) that allows passage of the cylindrical trunk through the mouth of the enclosure.

[0028] Once the cylindrical trunk is in the enclosure, the holding enclosure can be placed in a contracted state, or locked, where the trial is more securely held, so that the trial will not escape the holding enclosure as it is experiencing greater forces while being inserted and removed from the intervertebral space. This locking is effected by rotating a sleeve that surrounds the prongs. The bore of the sleeve is configured to press the prongs together when the sleeve is rotated a quarter turn (ninety degrees), and to allow them to separate when the sleeve is again (or in some embodiments, reverse) rotated a quarter turn (in either direction). (In some embodiments, either quarter turn is in either direction; e.g., in certain embodiments illustrated herein, the quarter turn that separates the prongs is a reverse rotation of the quarter turn that presses them together). In some embodiments, the sleeve is biased toward stopping its rotation at either the "locked" or "unlocked" states of the holding enclosure, by the cooperation of recesses on the extension's outer surface and corresponding spring plungers radially disposed to project from the sleeve's inner surface. In other embodiments, the sleeve stops its rotation at either the "locked" or "unlocked" states of the holding enclosure, due to radially inwardly directed screw heads on the sleeve's inner surface that ride in ninety-degree arc grooves on the extension's outer surface and that stop when the end of the groove is reached.

[0029] Further, the sleeve of the static trial holder preferably has on its exterior surface at least one stop protrusion that is positioned and dimensioned to extend dorsally or ventrally from the exterior surface when the holding enclosure is in its "locked" state, so that when the surgeon inserts the static trial into the intervertebral space, the stop protrusions prevent the

static trial from being inserted too far into the space (that is, so that the stop protrusions hit against the lips of the adjacent vertebral body endplates before the static trial is inserted too far).

[0030] It should be understood that when a static trial is being held (either when the holding enclosure is in its receptive state or in its contracted state), because the semicylindrical extents fit within the annular groove of the static trial, the static trial will not escape from the enclosure along the longitudinal axis of the cylindrical trunk. While the static trial holders are discussed herein as primarily used for manipulating the static trials, they are preferably is also useful for manipulating the distraction spacers described in the '127 application, in that the semicircular extents of the pincers preferably also interact with the annular grooves and cylindrical trunks of those distraction spacers in the same manner as described herein.

[0031] With regard to the dynamic trial described herein, the dynamic trial is provided primarily for distracting an intervertebral space according to the procedures described herein and/or for determining the appropriate size of an artificial intervertebral disc to be implanted (or whether a particular size can be implanted) into the distracted intervertebral space. While the distraction systems and methods described in the '127 application are also useful for distracting an intervertebral space, the dynamic trial is provided as an additional or alternate distraction tool. Further, while the static trials described herein as useful for determining the appropriate size of an artificial intervertebral disc to be implanted (or whether a particular size can be implanted), the dynamic trial is provided as an additional or alternate sizing tool.

[0032] The dynamic trial preferably includes a shaft having a bifurcated trial at a distal end. Each half of the bifurcated trial preferably has on its outwardly facing surface a convex dome that is shaped like the convex dome of the corresponding baseplate of the artificial intervertebral disc that the dynamic trial approximates. The shaft includes an inner shaft portion that centrally divides into upper and lower distal extensions that, from the point of division to their distal ends, are each biased toward positions in which they converge toward one another. The lower distal extension is connected to the lower half of the bifurcated trial, and the upper distal extension is connected to the upper half of the bifurcated trial. Preferably, the upper half is adjustably connected to the upper distal extension by a pivot pin that allows the upper half to rotate about a lateral axis that passes through the longitudinal and lateral center of the bifurcated trial. This axis of rotation allows the upper half, when separating from the lower half, to adjust to the orientation of the upper vertebral bone without causing the bone to hinge relative to the lower vertebral bone. In order to effect the separation of the upper and lower halves, the

shaft further includes an outer shaft portion that is translatable adjacent the inner shaft portion, the outer shaft portion having a pin that passes between the distal extensions.

[0033] The outer shaft portion is preferably translatable distally by the forward movement of a control knob near the proximal end of the shaft, and translatable proximally by backward
5 movement of the control knob. As the outer shaft portion is pushed distally, the pin is pushed distally to overcome the bias of the divided extensions to separate them and correspondingly separate the halves of the bifurcated trial. Preferably, markings are provided on the inner shaft portion to quantify the depth (to which the bifurcated trial has been expanded) corresponding to the distance that the outer shaft portion has been translated with respect to the inner shaft
10 portion. It is anticipated that the pushing force required to separate the halves will increase as they separate, due to the compression of the spine seeking to close the intervertebral space and the annulus seeking to prevent the adjacent vertebral discs from separating beyond a certain point. Therefore, to provide a mechanical advantage to the operator in the event that greater distraction is required, but the operator cannot push the control knob farther with unaided human
15 effort, a fine control knob is provided. The fine control knob is preferably threaded onto the proximal end of the inner shaft portion, proximal to the control knob. Thus, rotation of the fine control knob about the longitudinal axis of the inner shaft portion will cause the body of the fine control knob to press against the control knob to move it farther distally. The interference of the threads of the fine control knob-inner shaft portion interface prevents the fine control knob from
20 backing up proximally unless the fine control knob is reverse rotated to effect that result. Finally, the proximal end of the shaft is preferably flanged to serve as a slap hammer for impaction, if necessary for proper positioning of the bifurcated trial, and/or forced extraction of the bifurcated trial.

[0034] With further regard to the inserter/impactors described herein, the
25 inserter/impactors are provided primarily for holding, inserting, repositioning, removing, impacting, extracting, and otherwise manipulating an artificial intervertebral disc (or static trial) having features suitable for being manipulated by the inserter/impactors. Exemplary suitable artificial intervertebral discs are described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g.,
30 embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by the inserter/impactors, such features include those discussed above as being suitable features on the static trials and artificial intervertebral disc, namely, an anteriorly facing flat surface on the

second (e.g., lower) baseplate of the trial or disc, flanked by two anterioplaterally facing flat surfaces (one on each side of the anteriorly facing flat surface), and, to provide for holding of the trial or disc for an anterior insertion approach, a hole spaced from the anteriorly facing flat surface, the hole having a longitudinal axis parallel to the anteriorly facing flat surface.

5 [0035] The inserter/impactors include a shaft having a distal end that has angled flat surfaces corresponding to and fittable against the angled flat surfaces of the static trial or artificial intervertebral disc, and a holding pin that extends from the center flat surface along a longitudinal axis of the shaft, the pin having a distal end that bends downward. The holding pin is spring loaded in a central channel of the shaft, so that it is biased toward and against a central
10 flat surface (preferably, the bent end of the pin prevents it from entering the central channel). A flange, mechanically connected to the pin and translating adjacent the shaft, can be pushed distally to overcome the bias of the spring to space the pin away from the central flat surface. In this position, the pin can be inserted in the hole in the baseplate of the artificial intervertebral disc. Releasing the knob allows the spring to pull the pin back, causing the anteriorly facing
15 surface of the baseplate to be held against the central flat surface of the inserter/impactor and the anterioplaterally facing flat surfaces of the artificial intervertebral disc to be held against the other corresponding flat surfaces of the inserter/impactor. A knob on the inserter/impactor can be rotated about the longitudinal axis of the shaft to pull the pin tighter and lock its position to more securely hold the baseplate, and reverse rotated to unlock and loosen the pin. (In some
20 embodiments of the inserter/impactor having a wedge plate, the holding pin protrudes from a wedge-shaped extended surface of the distal end of the inserter/impactor and is restricted from upward movement with respect to the distal head by the presence of the wedge-shaped extended surface of the distal end of the inserter/impactor. More particularly, with any attempted upward movement of the holding pin, the pin encounters the upper surface of the channel in
25 which the pin travels, preventing any such upward movement.)

[0036] When the static trial or artificial intervertebral disc is held in this manner, rotation of the trial or disc about its longitudinal axis relative to the inserter/impactor is prevented by interference of the corners of the trial's or disc's flat surfaces and the corners of the
inserter/impactor's flat surfaces, similar to the manner in which a wrench holding a nut prevents
30 rotation of the nut relative to the wrench. Further, the holding of the trial or disc in this manner allows for some repositioning of the trial or disc in the intervertebral space via rotation of the trial or disc in either direction about the longitudinal axis of the intervertebral space. Further, in some embodiments of the inserter/impactor having a wedge plate, when the trial or disc is held in this

manner, rotation of the trial or disc about a lateral axis of the trial or disc relative to the inserter/impactor is prevented by interference of the inwardly facing surface of the first baseplate (e.g., upper baseplate) of the trial or disc and the corresponding surface (e.g., upper surface) of the wedge on the distal end, and by interference of the inwardly facing surface of the second
5 baseplate (e.g., lower baseplate) of the trial or disc and the corresponding surface (e.g., lower surface) of the wedge on the distal end. With regard to artificial discs, it is preferable that the wedge on the inserter/impactor will interfere between the first and second baseplates (e.g., upper and lower) so that the surfaces of the first and second baseplates align at a preferred 15 degrees angle of lordosis when the disc is held by the inserter/impactor.

10 [0037] Preferably, both of the baseplates of the static trial or disc have similarly configured flat surfaces, and both baseplates' flat surfaces fit against the angled flat surfaces of the inserter/impactor to provide for a more secure holding of the static trial or disc by the inserter/impactor. Also preferably, in order to provide for a holding of the static trial or disc for two additional (here, anteriolateral) insertion approaches, each static trial or disc also includes
15 two additional holes, one spaced apart from one of the anteriolaterally facing flat surfaces, and the other spaced apart from the other of the anteriolaterally facing flat surfaces. Accordingly, operation of the inserter/impactor can fit the holding pin into either of these two additional holes, and hold the anteriolaterally facing flat surface (the one associated with the hole into which the pin is fit) of the static trial or disc against the flat surface of the inserter/impactor opposite the pin.
20 It should be understood that preferably, in order to facilitate these two additional approaches, the angle separating the anteriorly facing flat surface of the static trial or disc and one of the anteriolaterally facing flat surfaces of the static trial or disc is equal to the angle separating the anteriorly facing flat surface and the other of the anteriolaterally facing flat surfaces.

[0038] Also preferably, as shown, the baseplates of each of the plurality of static trials
25 are appropriately lordotically angled relative to one another to ease insertion of the static trial into the intervertebral space and to mimic how the artificial intervertebral disc will typically be oriented as it is being inserted. In some embodiments, the inserter/impactor holds the artificial intervertebral disc by the lower baseplate such that the upper baseplate is permitted to adjust its degree of lordosis relative to the lower baseplate during insertion, as described in greater detail
30 below. In other embodiments, the inserter/impactor holds the baseplates in a fixed degree of lordosis relative to one another, as described in greater detail below.

[0039] With further regard to the repositioners/extractors described herein, each repositioner/extractor is provided primarily for repositioning and/or extracting a static trial or

artificial intervertebral disc having features suitable for being manipulated by the repositioner/extractor. Exemplary suitable artificial intervertebral discs are described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, 5 fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by each repositioner/extractor, such features include at least two holes extending longitudinally into one of the baseplates of the static trial or artificial intervertebral disc from the inwardly facing surface of the baseplate. More than two holes can be used to provide for multiple repositioning/extracting approaches. Preferably, in order for the 10 same repositioning/extracting tool to be used for multiple approaches on the same trial or artificial intervertebral disc, adjacent holes should be separated by the same distance separating other adjacent holes.

[0040] In order to engage the two holes, each repositioner/extractor has two pins extending in parallel from a central shaft, perpendicular to the longitudinal axis of the central 15 shaft. The pins are spaced to engage the two holes simultaneously, and each pin has a diameter smaller than the diameter of the hole it is to engage. Therefore, the pins can be inserted into the holes, and pulling or pushing on the central shaft along its longitudinal axis when the holes are engaged pulls or pushes the static trial or artificial intervertebral disc in the intervertebral space. Further, because two holes are engaged, the static trial or artificial 20 intervertebral disc can be rotated in either direction about a longitudinal axis passing through the intervertebral space, by rotating of the central shaft of the repositioner/extractor about its distal end, about an axis parallel to the longitudinal axes of the pins. A handle at a proximal end of the central shaft is useful for pushing or pulling on the shaft. A flange adjacent the proximal end of the shaft is useful for impaction (either with a distally directed force or a proximally directed 25 force), if necessary to manipulate the shaft.

[0041] On each repositioner/extractor, the pins are formed on prongs that extend laterally from the central shaft. The direction of the prongs, and the location of the pins relative to the central shaft, determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Further, the number and location of holes further determine 30 the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Accordingly, the present invention contemplates a variety of repositioner/extractors, and a variety of holes configurations, to provide the surgeon with a variety of possible surgical approach angles.

[0042] With further regard to the leveler described herein, the leveler is provided primarily for establishing a parallel orientation of the baseplates (relative to one another), and/or securing the purchase of the stabilizing spikes, of an artificial intervertebral disc having features suitable for being manipulated by the leveler. Exemplary suitable artificial intervertebral discs are described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by the leveler, such features include suitably formed inwardly facing surfaces of the baseplates of the artificial intervertebral disc.

[0043] More particularly, the leveler includes a shaft having a forked distal end formed by two opposing tongs that are symmetric to one another about a longitudinal axis of the shaft. Each of the tongs has an extent that initially curves laterally outward away from the shaft and from the other tong's extent, to define a central pocket forward of the shaft between the tongs' extents. Each tong's extent then resumes a distal direction to become parallel to the shaft and to the other tong's extent.

[0044] Each tong's extent has an upper surface and a lower surface. The upper surface is preferably shaped to conform against the inwardly facing surface of a first (e.g., upper) baseplate of an artificial intervertebral disc, and the lower surface is preferably shaped to conform against the inwardly facing surface of a second (e.g., lower) baseplate of the artificial intervertebral disc, so that insertion of the forked distal end of the leveler between the baseplates, with the central pocket of the distal end avoiding the central portion of the artificial intervertebral disc, and with the upper and lower surfaces so engaging the inwardly facing surfaces of the baseplates, causes the baseplates to be placed in parallel orientation with respect to one another. A handle is provided at a proximal end of the shaft for pushing, pulling, and otherwise manipulating the leveler as needed.

[0045] When the artificial intervertebral disc is inserted into the intervertebral space, its baseplates will typically be lordotically angled with respect to one another. The leveler can be applied to the artificial intervertebral disc to bring the baseplates parallel to one another. The forked distal end of the leveler is inserted so that the tongs' extents are placed between the inwardly facing surfaces of the baseplates, and so that the central pocket of the leveler avoids that portion of the artificial intervertebral disc that joins the baseplates. As the leveler is inserted, the tongs act as wedges to force the posterior portions of the baseplates away from one another.

Accordingly, as the posterior portions are being separated, the stabilizing spikes on the outwardly facing surfaces of the baseplates find or secure their purchase in the hard bone of the outer ring of the vertebral body endplates. When the forked distal end is fully seated, the extents of the tongs hold the baseplates parallel to one another, and so that the spikes are fully engaged in the endplates.

BRIEF DESCRIPTION OF THE DRAWINGS

[0046] Figs. 1a-f show front (Fig. 1a), side (Fig. 1b), perspective (Fig. 1c), top (Fig. 1d), bottom cutaway (Fig. 1e) and top cutaway (Fig. 1f) views of a static trial of the present invention. Figs. 1aa-ff show front (Fig. 1aa), side (Fig. 1bb), perspective (Fig. 1cc), top (Fig. 1dd), bottom cutaway (Fig. 1ee), and top cutaway (Fig. 1ff) views of an alternate static trial of the present invention.

[0047] Figs. 1g-n show front (Fig. 1g), side cutaway (Fig. 1h), top (Fig. 1i), side cutaway (Fig. 1j), bottom cutaway (Fig. 1k), top cutaway (Fig. 1l), bottom perspective (Fig. 1m), and top perspective (Fig. 1n) views of an exemplary artificial intervertebral disc of the present invention.

[0048] Figs. 2a-k show top (Fig. 2a), side (Fig. 2b), perspective (Fig. 2c), disassembly (Fig. 2d-j), and side cutaway (Fig. 2k) views of a static trial holder of the present invention.

[0049] Figs. 2aa-cc and 2kk show side (Fig. 2aa), top (Fig. 2bb), perspective (Fig. 2cc), and side cutaway (Fig. 2kk) views of an alternate static trial holder 2000 of the present invention. Figs. 2dd1, 2dd2, 2dd3, and 2ee-ff show a sleeve of the alternate static trial holder 2000 in side (Fig. 2dd1), top (Fig. 2dd2), side cutaway (Fig. 2dd3), front (Fig. 2ee), and back (with partial cutaway) (Fig. 2ff) views. Figs. 2gg-ii show an extension of the alternate static trial holder 2000 in top (Fig. 2gg), proximal cutaway (Fig. 2hh), side (Fig. 2ii), and distal cutaway (Fig. 2jj) views.

[0050] Figs. 2ll-nn show top (Fig. 2ll), side (Fig. 2mm), and perspective (Fig. 2nn) views of the alternate static trial holder of Figs. 2aa-kk holding an alternate static trial of Figures 1aa-ff from an anterior approach hold. Figs. 2oo-pp show top views of the alternate static trial holder of Figs. 2aa-kk holding an alternate static trial of Figures 1aa-ff from two anterior-lateral approach holds. Fig. 2qq shows a perspective view of the alternate static trial holder of Figs. 2aa-kk holding an alternate static trial of Figures 1aa-ff from the anterior-lateral approach hold of Fig. 2pp.

[0051] Figs. 3a-d show side (Fig. 3a), top (Fig. 3b), side cutaway (Fig. 3c), and perspective (Fig. 3d) views of a dynamic trial of the present invention.

[0052] Figs. 4a-d show side (Fig. 4a), top (Fig. 4b), side cutaway (Fig. 4c), and perspective (Fig. 4d) views of an inserter/impactor of the present invention.

[0053] Figs. 4e-h show side (Fig. 4e), top (Fig. 4f), side cutaway (Fig. 4g), and perspective (Fig. 4h) views of an inserter/impactor of the present invention holding a static trial of the present invention.

[0054] Figs. 4i-j show top views of an inserter/impactor of the present invention holding a static trial of the present invention in two alternative ways.

[0055] Figs. 4k-n show side (Fig. 4k), top (Fig. 4l), side cutaway (Fig. 4m), and perspective (Fig. 4n) views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention.

[0056] Figs. 4o-p show top views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention in two alternative ways.

[0057] Figs. 4aa-cc show side (Fig. 4aa), perspective (Fig. 4bb), and close-up perspective (Fig. 4cc) views of a wedge plate inserter/impactor of the present invention.

[0058] Figs. 4dd-4gg show bottom (Fig. 4dd), side (Fig. 4ee), top (Fig. 4ff), and side cutaway (Fig. 4gg) views of a distal end of a wedge plate inserter/impactor of the present invention.

[0059] Figs. 4hh-ii show top (Fig. 4hh) and side (Fig. 4ii) views of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

[0060] Figs. 4jj-ll show top (Fig. 4jj), side (Fig. 4kk), and side cutaway (Fig. 4ll) views of a distal end of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

[0061] Figs. 5a-c show side (Fig. 5a), top (Fig. 5b), and perspective (Fig. 5c) views of a symmetric repositioner/extractor of the present invention.

[0062] Figs. 5d-f show side (Fig. 5d), top (Fig. 5e), and perspective (Fig. 5f) views of an offset left repositioner/extractor of the present invention.

[0063] Figs. 5g-i show side (Fig. 5g), top (Fig. 5h), and perspective (Fig. 5i) views of an offset right repositioner/extractor of the present invention.

[0064] Figs. 5j-l show side (Fig. 5j), top (Fig. 5k), and perspective (Fig. 5l) views of an alternative offset left repositioner/extractor of the present invention.

[0065] Figs. 5m-o show side (Fig. 5m), top (Fig. 5n), and perspective (Fig. 5o) views of an alternative offset right repositioner/extractor of the present invention.

[0066] Figs. 5p-u show exemplary various possible repositioner/extractor approach angles with a three hole configuration of the present invention.

[0067] Figs. 5v-dd show exemplary various possible repositioner/extractor approach angles with a four hole configuration of the present invention.

5 [0068] Figs. 6a-e show bottom (Fig. 6a), side (Fig. 6b), front (Fig. 6c), top partial perspective (Fig. 6d), and bottom partial perspective (Fig. 6e) views of a leveler of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 [0069] While the invention will be described more fully hereinafter with reference to the accompanying drawings, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of the invention. Accordingly, the descriptions that follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the invention and not as limiting of such broad scope. Like numbers refer to similar features of like elements throughout.

15 [0070] Preferred embodiment of static trials of the present invention, and a preferred embodiment of an artificial intervertebral disc of the present invention, both for use with the instrumentation of the present invention, will now be described.

[0071] Referring now to Figs. 1a-f, a static trial of the present invention is shown in front (Fig. 1a), side (Fig. 1b), perspective (Fig. 1c), top (Fig. 1d), bottom cutaway (Fig. 1e) and top
20 cutaway (Fig. 1f) views. Referring now to Figs. 1aa-ff, an alternate static trial of the present invention is shown in front (Fig. 1aa), side (Fig. 1bb), perspective (Fig. 1cc), top (Fig. 1dd), bottom cutaway (Fig. 1ee) and top cutaway (Fig. 1ff) views. Referring now to Figs. 1g-n, an artificial intervertebral disc of the present invention is shown in front (Fig. 1g), side cutaway (Fig. 1h), top (Fig. 1i), side cutaway (Fig. 1j), bottom cutaway (Fig. 1k), top cutaway (Fig. 1l), bottom
25 perspective (Fig. 1m), and top perspective (Fig. 1n) views.

[0072] It should be understood that the illustration and reference herein to the artificial intervertebral disc shown in Figs. 1g-n is merely to show an example of one type of artificial intervertebral disc that is contemplated by, encompassed by, and suitable for use with, the present invention, and that such illustration and reference herein is not meant to limit the scope
30 of the present invention or limit the uses of the present invention. Rather, any other artificial intervertebral disc (or any other orthopedic device) having suitable features for being used with the instrumentation and methods described herein are contemplated by the present invention.

Indeed, the features suitable for manipulation (e.g., the angled flat surfaces and adjacent holes and inwardly facing surfaces) are encompassed by the present invention, regardless of to what orthopedic device they may be applied. Other exemplary suitable artificial intervertebral discs include, but are not limited to, the artificial intervertebral discs described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). It should be noted that, as can be seen from Figs. 1g-n, that the artificial intervertebral disc shown in Figs. 1g-n has features similar to those of these other suitable artificial intervertebral discs of the '160 and '528 applications, and it should be understood that such similar features are structurally and functionally as described in the '160 and '528 applications. Such similar features include an inwardly facing surface 164a of the upper baseplate 164a, and a convex structure 162 on the lower baseplate 168b, the convex structure 162 having an inwardly facing surface 164b.

[0073] And, while the instrumentation described herein (e.g., the static trials, static trial holders, dynamic trial, inserter/impactors, repositioners/extractors, and leveler) will be discussed for use with the artificial intervertebral disc of Figs. 1g-n, such discussions are merely by way of example and not intended to be limiting of their uses. Thus, it should be understood that the tools can be used with any of the artificial intervertebral discs disclosed in the '160 and '528 applications, or any other artificial intervertebral disc having (or being modifiable or modified to have) suitable features therefor. Moreover, it is anticipated that the features of the artificial intervertebral disc (e.g., the angled flat surfaces and accompanying holes and inwardly facing baseplate surfaces) and/or the static trials (e.g., the cylindrical trunks and angled flat surfaces and accompanying holes and/or engagement notches) that are used by the tools discussed herein to hold and/or manipulate these devices (such features, it should be noted, were first shown and disclosed in the '356, '585, '267, '160, and '528 applications) can be applied, individually or collectively or in various combinations, to other trials, spacers, artificial intervertebral discs or other orthopedic devices as stand-alone innovative features for enabling such trials, spacers, artificial intervertebral discs, or other orthopedic devices to be more efficiently and more effectively held and/or manipulated by the tools described herein or by other tools having suitable features. In addition, it should be understood that the invention encompasses artificial intervertebral discs, spacers, trials (static or dynamic), and/or other orthopedic devices, that have one or more of the features disclosed herein, in any combination,

and that the invention is therefore not limited to artificial intervertebral discs, spacers, trials, and/or other orthopedic devices having all of the features simultaneously.

[0074] Referring to Figs. 1a-f and 1aa-ff, a plurality of static trials 100,1000 are provided primarily for use in determining the appropriate size of an artificial intervertebral disc to be
5 implanted (or whether a particular size of the artificial intervertebral disc can be implanted) into the distracted intervertebral space (e.g., the artificial intervertebral disc 160 of Figs. 1g-n). Preferably, for each artificial intervertebral disc to be implanted, a plurality of sizes of the artificial intervertebral disc would be available. That is, preferably, a plurality of the same type of artificial intervertebral disc would be available, each of the plurality having a respective width and depth
10 dimension combination that allows it to fit within a correspondingly dimensioned intervertebral space. For example, the plurality of artificial intervertebral discs could include artificial intervertebral discs having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 discs. Accordingly, preferably, each of the plurality of static trials 100,1000 for use with a particular plurality of differently sized artificial intervertebral
15 discs would have a respective width and depth dimension set corresponding to the width and depth of a respective one of the plurality of differently sized artificial intervertebral discs. For example, the plurality of static trials 100,1000 for use with the set of artificial intervertebral discs described for example could include static trials having widths being either 35mm or 40mm, and depths ranging from 14mm to 18mm in 1mm increments, for a total of 10 static trials. It should
20 be understood that the artificial intervertebral discs and/or the static trials 100,1000 can be offered in a variety of dimensions without departing from the scope of the invention, and that the dimensions specifically identified and quantified herein are merely exemplary. Moreover, it should be understood that the set of static trials 100,1000 need not include the same number of trials for each artificial intervertebral disc in the set of artificial intervertebral discs, but rather,
25 none, one, or more than one trial can be included in the trial set for any particular artificial intervertebral disc in the set.

[0075] Each of the static trials 100,1000 shown is exemplary for all of the static trials in the plurality of static trials; preferably the static trials in the plurality differ from one another only with regard to overall dimensions as described above) includes at least one feature that can be
30 engaged by a tool. Suitable tools include, but are not limited to, the static trial holders described below, the inserter/impactors described below, and the repositioners/extractors described below.

[0076] Specifically, the static trial 100,1000 includes a recess 102,1020 that can be engaged by the opposing semicircular extents 216a-b,2160a-b of the static trial holder

200,2000. Preferably, this recess 102,1020 forms an annular groove 104,1040 that establishes a cylindrical trunk 106,1060 between the upper and lower baseplates 108a-b,1080a-b of the static trial 100,1000, such that the baseplates 108a-b,1080a-b extend as flanges 110a-b,110a-b from either end of the cylindrical trunk 106,1060. Accordingly, preferably, the opposing
5 semicircular extents 216a-b,2160a-b each have a thickness smaller than the width of the annular groove 104,1040, and as such fit into the annular groove 104,1040 to grip the cylindrical trunk 106,1060 between them. (Importantly, with regard to the alternate static trials 1000 being engaged by the alternate static trial holder 2000, as discussed in greater detail below, the body of the prongs 2140a-b (from which the semicircular extents 2160a-b extend) has a thickness
10 greater than the width of the annular groove 1040 (and as such does not fit within the annular groove) but small enough to be accommodated by the opposing notches 1320a-b of the alternate static trial 1000 as described below.)

[0077] In some embodiments, while not shown in Figs. 1a-f or Figs. 1aa-ff, it is also preferable that the annular groove 104,1040 radially widen outwardly, such that the walls
15 112,1120 of the annular groove 104,1040 are tapered toward one another with the increasing depth of the groove 104,1040, such that the floor 114,1140 of the groove 104,1040 is more narrow than the opening 116,1160 of the groove 104,1040. Accordingly, preferably, in such embodiments, each semicircular extent 216a-b,2160a-b correspondingly radially widens outwardly, such that the thinner portion of the extent 216a-b,2160a-b fits closer to the floor
20 114,1140 of the annular groove 104,1040, so that the tapered surfaces of the extents 216a-b,2160a-b compress against the tapered walls 112,1120 of the annular groove 104,1040 when the static trial 100,1000 is engaged by the static trial holder 200,2000. This taper locking provides for a secure grip so that the static trial 100,1000 can be manipulated accurately and efficiently.

[0078] In some embodiments, while not shown in Figs. 1a-f or Figs. 1aa-ff, it is also preferable that the floor of the annular groove 104,1040 of the cylindrical trunk 106,1060 be
25 ridged (e.g., have ridges that run parallel to the longitudinal axis of the cylindrical trunk), and the surfaces of the semicircular extents 216a-b,2160a-b of the static trial holder 200,2000 that compress against the floor of the annular groove 104,1040 when the static trial holder 200,2000
30 grips the static trial 100,1000 be correspondingly provided with ridges. The interlocking of the ridges of the static trial 100,1000 with the ridges of the static trial holder 200,2000 when the static trial 100,1000 is engaged prevents rotation of the static trial 100,1000 about the longitudinal axis of the cylindrical trunk 106,1060 with respect to the static trial holder 200,2000.

[0079] Preferably, as shown in Figs. 1aa-ff, each alternate static trial 1000 includes (on any alternate static trial surface that faces the desired engagement approach direction of the alternate static trial holder 2000) opposing recesses, preferably formed as upper and lower notches, an upper notch in the upper baseplate and a lower notch in the lower baseplate. For example, opposing notches 1320b and 1320e are on each of the anteriorly facing flat surfaces of the upper 1080a and lower 1080b baseplates. And, for example, opposing notches 1320a and 1320d are on one of the anterior-laterally facing flat surfaces of the upper 1080a and lower 1080b baseplates. And, for example, opposing notches 1320c and 1320f are on the other of the anterior-laterally facing flat surfaces of the upper 1080a and lower 1080b baseplates. Preferably, the notches 1320a-f are sized so that the opposing notches of each pair (1320a,d, 1320b,e, and 1320c,f) form a volume that closely accommodates the dimensions of the alternate static trial holder's 2000 prongs' 2140a-b cross-section. That is, as described below, the body of each prong 2140a-b is thicker than the semicircular extent 2160a-b that extends from the body, and as such, whereas the semicircular extents 2160a-b fit into the annular groove 1040, the prongs 2140a-b do not because the depth 2260 of their cross-section (described below) is greater than the width of the annular groove opening 1160. However, each notch pair (1320a,d, 1320b,e, and 1320c,f) accommodates this greater thickness, in that each notch 1320a-f has a depth 1340, and, when the two notch depths 1340 of the opposing notches of the notch pair are taken together with the width of the annular groove 1040, the combined distance accommodates the depth 2260 of the static trial holder's 2000 prongs' 2140a-b cross-section. Further, each notch 1320a-f has a width 1360 that accommodates the width 2240 of the alternate static trial holder's 2000 prongs' 2140a-b cross-section. (It should be noted that the width 1360 accommodates the width 2240 of the alternate static trial holder's 2000 prongs' 2140a-b cross-section even when the prongs 2140a-b are separated to place the holding enclosure 2100 in an expanded state as described below. This enables the notches 1320a-f to accommodate the width 2240 of the prongs' cross-section as the cylindrical trunk 1060 of the static trial 1000 is being snapped into the holding enclosure 2100 as described below.) As such, as the opposing semicircular extents 2160a-b of the alternate static trial holder 2000 are placed into the annular groove 1040, the bodies of the prongs 2140a-b pass into the notches of the pair so that the semicircular extents 2160a-b can continue into the annular groove 1040 and be seated around the cylindrical trunk 1060. More specifically, the prongs 2140a-b of the alternate static trial holder 2000 fit into the notches above and below it (e.g., 1320b and 1320e for an anterior approach; 1320a and 1320d for an anterior-lateral approach; and 1320c and 1320f for another anterior-lateral approach).

Once the prongs 2140a-b are fitted within the notch pair, interference between the prongs 2140a-b and the notch walls limits or prevents rotation of the alternate static trial 1000 about a longitudinal axis (e.g., an axis parallel to the longitudinal axis of the cylindrical trunk 1060) with respect to the alternate static trial holder 2000.

5 [0080] It should be understood that configurations having more or fewer notches, and in a variety of locations, are contemplated by the invention, and the detailed descriptions of only one type of notch configuration is not meant to limit the invention to only this configuration. Importantly, the invention encompasses using a single notch in a baseplate, a single notch pair, or any number of notches or notch pairs, formed in any suitable manner with any suitable
10 dimensions, in any number of locations on a spacer, a trial or an artificial intervertebral disc (not limited to locations on the baseplates), for purposes of enabling the spacer, trial, or disc to be engaged by a manipulation instrument (not limited to a static trial holder) that engages the notch, for the purpose of limiting rotation of the spacer, trial, or disc (or other orthopedic implant) with respect to the instrument or for any other purpose, and/or to enable the surgeon to work from a
15 variety of approaches. For example, the notch configuration described herein, in cooperation with the alternate static trial holder, provides the surgeon with the ability to work from a directly anterior approach, as well as two anteriolateral approaches. It should be understood that additional notch configurations can enable the surgeon to work from a directly posterior approach, posteriolateral approaches, directly lateral approaches, or anteriolateral approaches
20 that are different than those illustrated. For example, the placement of one or more suitably spaced notches (or the addition of one or more notches) on the posterior edge, and/or one or both of the lateral edges of one or both of the baseplates, would enable the surgeon to use the alternate static trial holder of the present invention to achieve such approaches.

[0081] Additionally with regard to features that can be engaged by a tool, each of the
25 static trials 100,1000 includes at least one feature that can be engaged by a tool that preferably is also used to engage the artificial intervertebral disc that the trial approximates. Suitable tools that can engage both the trials and the artificial intervertebral disc include, but are not limited to, the inserter/impactors described below. Specifically, for being engaged by the inserter/impactors 400,4000, each static trial 100,1000 and artificial intervertebral disc 160
30 includes an anteriorly facing flat surface 120b,1200b,180b, flanked by two anteriolaterally facing flat surfaces 120a,1200a,180a and 120c,1200c,180c (one on each side of the anteriorly facing flat surface 120b,1200b,180b), and, to provide for holding of the static trial 100,1000 or disc 160 for an anterior insertion approach, a hole 122b,1220b,182b spaced from the anteriorly facing flat

surface 120b,1200b,180b, the hole 122b,1220b,182b having a longitudinal axis parallel to the anteriorly facing flat surface 120b,1200b,180b.

[0082] The holding pin 408,4080 of the inserter/impactor 400,4000 fits within the hole 122b,1220b,182b, and the angled flat surfaces 120a-c,1200a-c,180a-c of the static trial 100,1000 or disc 160 fit against the correspondingly angled flat surfaces 420a-c,4200a-c of the inserter/impactor 400,4000, and operation of the inserter/impactor 400,4000 pulls the holding pin 408,4080 toward the flat surface 120b,1200b,180b of the inserter/impactor 400,4000 opposite the pin 408,4080, to rigidly hold the static trial 100,1000 or disc 160 by the structure of the static trial 100,1000 or disc 160 having the hole 122b,1220b,182b (e.g., the baseplate 108b,1080b,168b).

[0083] When the static trial 100,1000 or disc 160 is held in this manner, rotation of the static trial 100,1000 or disc 160 about a longitudinal axis (of the static trial 100,1000 or disc 160) relative to the inserter/impactor 400,4000 is prevented by interference of the corners of the static trial's 100,1000 or disc's 160 flat surfaces 120a-c,1200a-c,180a-c and the corners of the inserter/impactor's 400,4000 flat surfaces 420a-c,4200a-c, similar to the manner in which a wrench holding a nut prevents rotation of the nut relative to the wrench. Further, the holding of the static trial 100,1000 or disc 160 in this manner allows for some repositioning of the static trial 100,1000 or disc 160 in the intervertebral space via rotation of the static trial 100,1000 or disc 160 in either direction about the longitudinal axis of the intervertebral space.

[0084] Further, with regard to the wedge plate inserter/impactor 4000, when the static trial 100,1000 or disc 160 is held in this manner, rotation of the static trial 100,1000 or disc 160 about a lateral axis (of the static trial 100,1000 or disc 160) relative to the inserter/impactor 4000 is prevented by interference of the inwardly facing surface (e.g., 164a) of the first baseplate (e.g., upper baseplate) of the static trial 100,1000 or disc 160 and the upper surface 4200g of the wedge on the distal end 4040, and by interference of the inwardly facing surface (e.g., 164b) of the second baseplate (e.g., lower baseplate) of the static trial 100,1000 or disc 160 and the lower surface 4200h of the wedge on the distal end 4040. Accordingly, the holding of the static trial 100,1000 or disc 160 in this manner allows for some repositioning of the static trial 100,1000 or disc 160 in the intervertebral space via rotation of the static trial 100,1000 or disc 160 in either direction about the longitudinal or latitudinal axis of the intervertebral space.

[0085] Preferably, both of the baseplates of the static trial 100,1000 or disc 160 have similarly configured flat surfaces. For example, the lower baseplate's 108b,1080b,168b flat surfaces 120a-c,1200a-c,180a-c have similarly configured and similarly oriented counterpart flat

surfaces 120d-f, 1200d-f, 180d-f on the upper baseplate 108a, 1080a, 168a. Further preferably, both baseplates' 108a-b, 1080a, 168a-b flat surfaces 120a-f, 1200a-f, 180a-f face the angled flat surfaces 420a-c, 4200a-f of the inserter/impactor 400, 4000 when the static trial 100, 1000 or disc 160 is held by the inserter/impactor 400, 4000. For example, in an anterior approach for the trial 100, 1000 (as shown in Figs. 4e-h, showing the trial 100 being held by the inserter/impactor 400 as an example for of how either trial 100, 1000 can be held by either inserter/impactor 400, 4000), 120a, 1200a and 120d, 1200d facing 420a (or 4200a and 4200d), 120b, 1200b and 120e, 1200e facing 420b (or 4200b and 4200e), and 120c, 1200c and 120f, 1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in Figs. 4k-n, showing the disc 160 being held by the inserter/impactor 400 as an example for of how the disc 160 can be held by either inserter/impactor 400, 4000), 180a and 180d facing 420a (or 4200a and 4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (or 4200c and 4200f).

[0086] It should be noted that preferably, when the static trial 100, 1000 is held by the inserter/impactor 400, 4000, the flat surfaces 120a-c, 1200a-c and the counterpart flat surfaces 120d-f, 1200d-f are tightly held against the angled flat surfaces 420a-c, 4200a-f of the inserter/impactor 400, 4000 as described above. It is also preferable that the baseplates 108a-b, 1080a-b of each of the plurality of static trials 100, 1000 be appropriately lordotically angled relative to one another to ease insertion of the static trial 100, 1000 into the intervertebral space and to mimic how the artificial intervertebral disc 160 will typically be oriented as it is being inserted using the inserter/impactor 400, 4000. While not shown in Figs. 1a-f or Figs. 1aa-ff, in some embodiments, when the static trials 100, 1000 are formed in such a lordotically oriented configuration, it is preferable that the flat surfaces 120d-f, 1200d-f on the first (e.g., upper) baseplate 108a, 1080a be parallel to the flat surfaces 120a-c, 1200a-c of the second (e.g., lower) baseplate 108b, 1080b in the static trial's 100, 1000 appropriately lordotically oriented configuration, so that when the static trial 100, 1000 is held tightly by the inserter/impactor 400, 4000, the flat surfaces 120a-f, 1200a-f are flush with the flat surfaces 420a-c, 4200a-f of the inserter/impactor 400, 4000 even though the baseplates 108a-b, 1080a-b are lordotically angled with respect to one another.

[0087] With regard to the inserter/impactor 400, by contrast, preferably, when the artificial intervertebral disc 160 is held by the inserter/impactor 400, the flat surfaces 180a-c are tightly held against the angled flat surfaces 420a-c of the inserter/impactor 400 as described above, but the counterpart flat surfaces 180d-f are loosely held against the angled flat surfaces

420a-c of the inserter/impactor 400. As such, the structure of the artificial intervertebral disc 160 having the counterpart flat surfaces 180d-f (e.g., the upper baseplate 168a) is able to angulate and rotate to a limited extent relative to the structure of the artificial intervertebral disc 160 having the flat surfaces 180a-c. This permits the artificial intervertebral disc 160 to adjust to the intervertebral space (e.g., to the angulation of the adjacent vertebral endplates, defining the intervertebral space, relative to one another) as it is being inserted therein. That is, typically, the adjacent vertebral endplates will be lordotically angled with respect to one another as a result of the intervertebral space being prepared and distracted. As the artificial intervertebral disc 160 is then inserted into the intervertebral space using the inserter/impactor 400, then, the baseplates 168a-b will be permitted to lordotically angle with respect to one another to squeeze into the intervertebral space.

[0088] With regard to the wedge plate inserter/impactor 4000, when the artificial intervertebral disc 160 is held by the inserter/impactor 4000, the wedge surfaces of the distal end 4040 protrude from a distance midway with respect to the top and bottom of the distal end 4040 and span (e.g., right to left or vice-versa) the entire distal face of the distal end 4040, and the surfaces 4200d-f above the wedge on the distal end 4040 are respectively perpendicular to the wedge's upper surface 4200g such that each is disposed in parallel with its respective corresponding surface of the disc 160 when the disc 160 is held by the inserter/impactor 4000 at the appropriate lordosis angle. (And, accordingly, are angled approximately 15 degrees with respect to the surfaces below the wedge 4200a-c.)

[0089] Preferably, for an anterior approach, the wedge-shaped extension 4042 is designed and shaped to fit with its antero-lateral confronting surfaces (4200d,f and 4200a,c) tightly against the correspondingly antero-laterally facing surfaces (180d,f and 180a,c) of the disc 160, but such that its anterior confronting surfaces (4200e and 4200b) are slightly spaced from the anteriorly facing surfaces (180d and 180b) of the disc 160, when the disc is held by the inserter/impactor 4000. This is primarily to address manufacturing issues (in some instances, tolerances may not be adequately defined to ensure that all of those surfaces fit tightly against their corresponding surfaces), so that if there are manufacturing anomalies, any slight tolerance differences that may exist are nevertheless still adequate to ensure at least the tight fitting of the antero-lateral confronting surfaces, so that manipulation of the disc 160 is possible (e.g., in the manner of a wrench against an angled nut). This can be achieved, e.g., by designing the anterior confronting surfaces (4200e and 4200b) to each be slightly greater in length than the corresponding anteriorly facing surfaces (180e and 180b) of the disc baseplates, while still being

angled with respect to the antero-lateral confronting surfaces (4200d,f and 4200a,c) at the same angle the antero-laterally facing surfaces (180d,f and 180a,c) of the disc baseplates are angled with respect to the anteriorly facing surfaces (180e and 180b) of the disc. The increased length of the anterior confronting surfaces on the wedge extension results in the slight clearance
 5 between the anteriorly facing surfaces (180e and 180b) of the disc and the corresponding anterior confronting surface (4200e and 4200b) of the wedged distal end, thereby ensuring that the disc will be fully seated against the antero-lateral confronting surfaces of the distal end despite possible manufacturing, material or other inevitable variations in tolerances of the artificial intervertebral disc or the inserter/impactor. As noted above, similar in this regard to the
 10 manner in which a wrench engages a nut, this fitting increases the mechanical advantage toward repositioning the disc in the intervertebral space. It should be noted, inasmuch as the inserter/impactor 4000 described herein can engage the disc from the antero-lateral angles as well, the anterior confronting surfaces (4200e and 4200b) should also be longer than the antero-laterally facing surfaces (180d,f and 180a,c) of the disc, so that a similar fitting occurs when the
 15 disc is held from the antero-lateral angles. Stated broadly, the primary confronting surfaces (e.g., the anterior confronting surfaces) of the inserter/impactor are preferably slightly longer than the primary confronted surfaces (e.g., anteriorly facing surfaces) of the disc for any given holding orientation.

[0090] In order to provide for a holding of the static trial 100,1000 or disc 160 for two
 20 additional (here, anteriolateral) insertion approaches, each static trial 100,1000 or disc 160 also preferably includes two additional holes 122a,1220a,182a and 122c,1220c,182c, one (e.g., 122a,1220a,182a) spaced apart from one of the anteriolaterally facing flat surfaces (e.g., 120a,1200a,180a), and the other (e.g., 122c,1220c,182c) spaced apart from the other of the anteriolaterally facing flat surfaces (e.g., 120c,1200c,180c). Accordingly, operation of the
 25 inserter/impactor 400,4000 can fit the holding pin 408,4080 into either of these two additional holes 122a,1220a,182a or 122c,1220c,182c, and hold the associated anteriolaterally facing flat surface (the one associated with the hole into which the pin 408,4080 is fit) of the static trial 100,1000 or disc 160 against the flat surface of the inserter/impactor 400,4000 opposite the pin 408,4080. For example, in a first anteriolateral approach for the trial 100,1000 (as shown in Fig.
 30 4i as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d not confronted, 120b,1200b and 120e,1200e facing 420a (or 4200a and 4200d), and 120c,1200c and 120f,1200f facing 420b (or 4200b and 4200e), and a first anteriolateral approach for the disc 160 (as shown in Fig. 4o as an example of the

how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d not confronted, 180b and 180e facing 420a (or 4200a and 4200d), and 180c and 180f facing 420b (or 4200b and 4200e). And, for example, in a second anteriolateral approach for the trial 100 (as shown in Fig. 4j as an example of how either trial 100,1000 can be engaged by either
5 inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420b (or 4200b and 4200e), 120b,1200b and 120e,1200e facing 420c (or 4200c and 4200f), and 120c,1200c and 120f,1200f not confronted, and a second anteriolateral approach for the disc 160 (as shown in Fig. 4p as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420b (or 4200b and 4200e), 180b and 180e facing 420c (or 4200c and 4200f), and
10 180c and 180f not confronted.

[0091] It should be understood that preferably, in order to facilitate these additional approaches, the angle separating the anteriorly facing flat surface of the static trial 100,1000 or disc 160 and one of the anteriolaterally facing flat surfaces of the static trial 100,1000 or disc 160 is equal to the angle separating the anteriorly facing flat surface and the other of the
15 anteriolaterally facing flat surfaces. Preferably, the surfaces are angled with respect to one another at an angle of 33.4 degrees.

[0092] It should also be understood that the inclusion of additional adjacent angulated surfaces and/or additional notches (or placing the angulated surfaces or notches in other locations on the trial or disc), and/or including corresponding holes adjacent to such angulated
20 surfaces or notches, can provide the surgeon with additional approaches, e.g., other anteriolateral approaches, directly lateral approaches, posteriolateral approaches, and/or directly posterior approaches. For example, a trial or disc can have angled surfaces (and corresponding holes) along the entire perimeter of one or both of the baseplates, and thus enable the surgeon to engage the trial or disc from a number of angles, including anterior, posterior, lateral,
25 anteriolateral, and posteriolateral angles. Or, for example, a trial (or disc) can have notches located on directly laterally facing surfaces or posterior surfaces or posterior-laterally facing surfaces, and thus enable the surgeon to engage the trial (or disc) with a static trial holder from a number of angles, including anterior, posterior, lateral, anteriolateral, and posteriolateral angles. (It should be noted that, while the opposing notches of the alternate static trials are shown
30 formed in conjunction with the angulated surfaces of the baseplates, neither the number nor the placement of the opposing notches need coincide or be related to the number or placement of the angulated surfaces of the baseplates. For example, the notches can be applied to a trial or disc having curved approach surfaces.)

[0093] Additionally with regard to features that can be engaged by a tool, each of the static trials 100,1000 includes at least one feature that can be engaged by a tool that preferably is also used to engage the artificial intervertebral disc that the trial approximates. Suitable tools that can engage both the trial and the artificial intervertebral disc include, but are not limited to, the repositioners/extractors 500,510,520,530,540 described below. Specifically, for being engaged by the repositioners/extractors, each static trial 100,1000 and artificial intervertebral disc 160 includes at least two holes extending longitudinally into one of the baseplates of the static trial 100,1000 or artificial intervertebral disc 160 from the inwardly facing surface of the baseplate. More than two holes can be used to provide for multiple repositioning/extracting approaches. Preferably, in order for the same repositioning/extracting tool to be used for multiple approaches on the same trial or artificial intervertebral disc, adjacent holes should be separated by the same distance separating other adjacent holes.

[0094] As discussed in greater detail below with regard to the repositioners/extractors 500,510,520,530,540, in order to engage two of the holes, each repositioner/extractor has two pins extending in parallel from a central shaft, perpendicular to the longitudinal axis of the central shaft. The pins are spaced to engage the two holes simultaneously, and each pin has a diameter smaller than the diameter of the hole it is to engage. Therefore, the pins can be inserted into the holes, and pulling or pushing on the central shaft along its longitudinal axis when the holes are engaged pulls or pushes the static trial or artificial intervertebral disc in the intervertebral space. Further, because two holes are engaged, the static trial or artificial intervertebral disc can be rotated in either direction about a longitudinal axis passing through the intervertebral space, by rotating the central shaft of the repositioner/extractor about its distal end, about an axis parallel to the longitudinal axes of the pins. A handle at a proximal end of the central shaft is useful for pushing or pulling on the shaft. A flange adjacent the proximal end of the shaft is useful for impaction (either with a distally directed force or a proximally directed force), if necessary to manipulate the shaft.

[0095] On each repositioner/extractor, the pins are formed on prongs that extend laterally from the central shaft. The direction of the prongs, and the location of the pins relative to the central shaft, determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Further, the number and location of holes further determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Accordingly, the present invention contemplates a variety of repositioner/extractors, and a

variety of holes configurations, to provide the surgeon with a variety of possible surgical approach angles.

[0096] As described in greater detail below, three repositioner/extractors are illustrated and described (symmetric, offset left, and offset right) for example,, and, for example, two hole configurations are illustrated and described. Referring again to Figs. 1a-n and Figs. 1aa-ff, a first hole configuration includes the hole configuration described above, that is, three holes on one of the baseplates (e.g., the lower baseplate 108b,1080b,168b), the holes being configured so that a first hole 122b,1220b,182b is located in the anterior-posterior plane, and the adjacent (second 122a,1220a,182a and third 122c,1220c,182c) holes are located in respective opposing anterioplateral planes on either side of the first hole 122b,1220b,182b. (This hole configuration is also shown in Figs. 5p-u, each of which shows a top cutaway view of the artificial intervertebral disc 160 of Figs. 1g-n, showing its lower baseplate 168b, having the first hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the lower baseplate 168b shows the first hole 182b, the second hole 182a, and the third hole 182c of the first hole configuration.)

[0097] Referring again to Figs. 1a-n, a second hole configuration includes four holes on one of the baseplates (e.g., the upper baseplate 108a,168a), the holes being configured so that first (e.g., 130c,190c) and second (e.g., 130b,190b) holes straddle the anterior-posterior plane, a third hole (e.g., 130d,190d) is located so that the third hole and the first hole straddle one of the opposing anterioplateral planes, and a fourth hole (e.g., 130a,190a) is located so that the fourth hole and the second hole straddle the other of the opposing anterioplateral planes. While this second hole configuration is not illustrated with regard to the static trials 1000, it should be understood that the static trials 1000 can be configured with such second hole configuration, or any other hole configuration, without departing from the scope of the present invention. (It should be noted that, while the opposing notches of the static trials 1000 are shown formed in conjunction with the holes in the baseplates, neither the number nor the placement of the opposing notches need coincide or be related to the number or placement of the holes in the baseplates.) (This second hole configuration is also shown in Figs. 5v-dd, each of which shows a bottom cutaway view of the artificial intervertebral disc of Figs. 1g-n, showing its upper baseplate 168a, having the second hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the upper baseplate shows the first hole 190c, the second hole 190b, the third hole 190d, and the fourth hole 190a, of the second hole configuration.)

[0098] It should be understood that configurations having more or fewer holes, and in a variety of locations, are contemplated by the invention, and the detailed descriptions of only two hole configurations is not meant to limit the invention to only these two configurations.

Importantly, the invention encompasses using a hole or any number of holes, bored at any
5 suitable angle, whether parallel to other holes or not, in any number of locations on a spacer, a trial or an artificial intervertebral disc (not limited to locations on the baseplates), for purposes of enabling the spacer, trial, or disc to be engaged by a manipulation instrument (not limited to a repositioner/extractor) that engages the hole, and/or to enable the surgeon to work from a variety of approaches. For example, as described in more detail below, the first and second hole
10 configurations described herein, in cooperation with the repositioner/extractors, provide the surgeon with the ability to work from a directly anterior approach, as well as several anteriolateral approaches. It should be understood that additional hole configurations can enable the surgeon to work from a directly posterior approach, posteriolateral approaches, directly lateral approaches, or anteriolateral approaches that are different than those illustrated. For example,
15 the placement of one or more suitably spaced holes (or the addition of one or more holes) on the posterior edge, and/or one or both of the lateral edges of one or both of the baseplates, would enable the surgeon to use the repositioner/extractors of the present invention to achieve such approaches.

[0099] Thus, it can be seen that each of the repositioner/extractors can be used in more
20 than one manner depending on the tool desired and the approach desired. These manners are described in greater detail below and illustrated in Figs. 5p-dd with regard to the detailed description of the repositioners/extractors.

[00100] Also preferably, the baseplates 108a-b, 1080a-b of each of the plurality of static trials 100, 1000 preferably has a convex dome 124a-b, 1240a-b on its outwardly facing
25 surface 126a-b, 1260a-b that is shaped like the convex dome 184a-b on the outwardly facing surface 186a-b of the corresponding baseplate 168a-b of the artificial intervertebral disc 160 that the static trial 100, 1000 approximates. Preferably, each convex dome 124a-b, 1240a-b is smooth, rather than having a porous coating that is preferred for the convex domes 184a-b of the artificial intervertebral disc 160, and each outwardly facing surface 126a-b, 1260a-b does not
30 have stabilizing spikes such as the stabilizing spikes 188a-b on the outwardly facing surfaces 186a-b of the artificial intervertebral disc 160. The omission of these device stabilizing and bone ingrowth encouraging structures and surfaces on the static trials 100, 1000 enables the surgeon

to test the size of the artificial intervertebral disc 160 to be implanted without traumatically engaging the vertebral body endplates.

[00101] Accordingly, the surgeon can prepare and distract the intervertebral space, and then insert and remove at least one of the static trials (or more, as necessary) to find the size that is most appropriate for the intervertebral space.

[00102] Preferred embodiments of static trial holders of the present invention will now be described.

[00103] Referring to Figs. 2a-c and 2k, a static trial holder 200 of the present invention is shown in side (Fig. 2a), top (Fig. 2b), perspective (Fig. 2c), and side cutaway (Fig. 2k) views. In addition, referring to Figs. 2d-f, a sleeve of the static trial holder is shown in side cutaway (Fig. 2d), front (Fig. 2e), and back (with partial cutaway) (Fig. 2f) views. In addition, referring to Figs. 2g-i, an extension of the static trial holder is shown in top (Fig. 2g), proximal cutaway (Fig. 2h), side (Fig. 2i), and distal cutaway (Fig. 2j) views.

[00104] Referring to Figs. 2aa-cc and 2kk, an alternate static trial holder 2000 of the present invention is shown in side (Fig. 2aa), top (Fig. 2bb), perspective (Fig. 2cc), and side cutaway (Fig. 2kk) views. In addition, referring to Figs. 2dd1, 2dd2, 2dd3, and 2ee-ff, a sleeve of the alternate static trial holder 2000 is shown in side (Fig. 2dd1), top (Fig. 2dd2), side cutaway (Fig. 2dd3), front (Fig. 2ee), and back (with partial cutaway) (Fig. 2ff) views. In addition, referring to Figs. 2gg-ii, an extension of the alternate static trial holder 2000 is shown in top (Fig. 2gg), proximal cutaway (Fig. 2hh), side (Fig. 2ii), and distal cutaway (Fig. 2jj) views.

[00105] The static trial holders 200,2000 are provided primarily for use in holding, inserting and removing the static trials 100,1000 described herein, or distraction spacers having suitable features therefor, such as the distraction spacers disclosed in the '127 application.

[00106] More specifically, each static trial holder 200,2000 includes a handle 202,2020, an extension 204,2040, and a sleeve 206,2060. As shown in Fig. 2k and 2kk, the handle 202,2020 and the extension 204,2040 are fixed to one another (preferably by the distal end of the handle 202,2020 being fixed to the proximal end of the extension 204,2040) to form a shaft 208,2080. The sleeve 206,2060 surrounds the extension 204,2040 and is rotatable with respect to the handle 202,2040 and the extension 204,2040 about the longitudinal axis of the shaft 208,2080. The handle 202,2020 preferably has an flange 232,2320 at its proximal end for use in applying a distally or proximally directed force to position the static trial 100,1000 (or distraction spacer) into or out of the intervertebral space, and/or for use in helping the surgeon

rotate the sleeve 206,2060 with respect to the extension 204,2040 (by engaging the flange 232,2320 and the control knob 219,2190 described below).

[00107] The distal end of the extension 204,2040 forms a contractable and expandable holding enclosure 210,2100 in that the distal end is divided at a fulcrum 212,2120 into two prongs 214a-b,2140a-b, each of which terminates in a semicircular extent 216a-b,2160a-b, each of which has a tapered end 215a-b,2150a-b. The extents 216a-b,2160a-b are oriented such that the tapered ends 215a-b,2150a-b face one another to define a radially inwardly tapering mouth 213,2130, and such that the semicircular openings oppose one another to define the holding enclosure 210,2100. The prongs 214a-b,2140a-b are spring biased toward a neutral position (preferably by the formation of the fulcrum 212,2120 in combination with the strength of the material of which the extension 204,2040 is made) such that the holding enclosure 210,2100 is spring biased to a receptive state (described below), but the prongs 214a-b,2140a-b can be brought together to contract the holding enclosure 210,2100 to a contracted state, (described below) or the prongs 214a-b,2140a-b can be further separated to expand the holding enclosure 210,2100 to an expanded state (described below).

[00108] When the holding enclosure 210,2100 is in the receptive state, the width of the mouth 213,2130 of the holding enclosure 210,2100 does not accommodate the diameter of the cylindrical trunk 106,1060 of the static trial 100,1000 (or distraction spacer) for passage therethrough. However, from this receptive state, the mouth 213,2130 can be temporarily widened (placing the holding enclosure 210,2100 in its expanded state) to accommodate the diameter (for passage of the cylindrical trunk 106,1060 through the mouth 213,2130), if a sufficient force is applied to overcome the neutral position bias of the prongs 214a-b,2140a-b and thus widen the mouth 213,2130. (Preferably, there is enough space between the outer surfaces of the prongs 214a-b,2140a-b and the inner surface of the bore 218,2180 of the sleeve, when the prongs 214a-b,2140a-b are in their neutral position, so that the prongs 214a-b,2140a-b can be separated without interference.) The sufficient force can be applied by pressing the cylindrical trunk 106,1060 against the tapered ends 215a-b,2150a-b of the mouth 213,2130, in that the separating force component of the radially inward force of the pressing will be applied to the semicircular extents 216a-b,2160a-b by the taper of the tapered ends 215a-b,2150a-b. Because the holding enclosure 210,2100 is biased toward the receptive state, after the cylindrical trunk 106,1060 is passed through the mouth 213,2130 and into the holding enclosure 210,2100, the holding enclosure 210,2100 will return to its receptive state in which the width of the mouth 213,2130 does not allow passage of the cylindrical trunk 106,1060 without the

sufficient force. Preferably, the force required to widen the mouth 213,2130 is greater than gravity and/or the greatest force that will be experienced by moving the static trial holder 200,2000 prior to placing the holding enclosure 210,2100 in the contracted state. Therefore, once the cylindrical trunk 106,1060 is in the holding enclosure 210,2100, even before the
5 holding enclosure 210,2100 is placed in its contracted state, the cylindrical trunk 106,1060 will not escape the holding enclosure 210,2100 as the static trial holder 200,2000 is oriented with the holding enclosure 210,2100 downward, or is moved about.

[00109] It should be understood that when the static trial 100,1000 (or distraction spacer) is being held (either when the holding enclosure 210,2100 is in its receptive state or in
10 its contracted state discussed below), because the semicylindrical extents 216a-b,2160a-b fit within the annular groove 104,1040 of the static trial 100,1000 (or distraction spacer), the static trial 100,1000 (or distraction spacer) will not escape from the enclosure along the longitudinal axis of the cylindrical trunk 106,1060. That is, as noted above, the recess 102,1020 of each static trial 100,1000 (or distraction spacer) forms an annular groove 104,1040 that establishes
15 the cylindrical trunk 106,1060 between the baseplates of the static trial (or distraction spacer), such that the baseplates extend as flanges from either end of the cylindrical trunk 106,1060. Accordingly, preferably, the opposing semicircular extents each have a thickness smaller than the width of the annular groove 104,1040, and as such fit into the annular groove 104,1040 to engage the cylindrical trunk 106,1060 between them.

[00110] In some embodiments, while not shown in Figs. 1a-f or Figs. 1aa-ff or Figs. 2a-k or Figs. 2aa-kk, it is preferable that the annular groove 104,1040 radially widen outwardly, such that the walls of the annular groove 104,1040 taper toward one another with the increasing depth of the groove, such that the floor of the groove is more narrow than the opening 116,1160 of the groove. Accordingly, preferably, in such embodiments, each semicircular extent
20 216a-b,2160a-b correspondingly radially widens outwardly, such that the thinner portion of the extent 216a-b,2160a-b fits closer to the floor of the annular groove 104,1040, so that the tapered surfaces 215a-b,2150a-b of the extents 216a-b,2160a-b compress against the tapered walls of the annular groove 104,1040 when the static trial 100,1000 is engaged by the static trial holder 200,2000. This taper locking provides for a secure grip so that the static trial 100,1000 can be
25 manipulated accurately and efficiently.

[00111] In some embodiments, while not shown in Figs. 1a-f or Figs. 1aa-ff or Figs. 2a-k or Figs. 2aa-kk, it is also preferable that the floor of the annular groove 104,1040 of the cylindrical trunk 106,1060 be ridged (e.g., have ridges that run parallel to the longitudinal axis

of the cylindrical trunk), and the surfaces of the semicircular extents 216a-b, 2160a-b of the static trial holder 200,2000 that compress against the floor of the annular groove 104,1040 when the static trial holder 200,2000 engages the static trial 100,1000 be correspondingly provided with ridges. The interlocking of the ridges of the static trial 100,1000 with the ridges of the static trial holder 200,2000 when the static trial 100,1000 is engaged prevents rotation of the static trial 100,1000 about the longitudinal axis of the cylindrical trunk 106,1060 with respect to the static trial holder 200,2000.

[00112] In order to more tightly hold the static trial 100,1000 (or distraction spacer) for manipulation of the static trial 100,1000 (or distraction spacer) during surgical procedures in which greater forces will be experienced by the static trial 100,1000 (or distraction spacer) and the static trial holder 200,2000, the holding enclosure 210,2100 can be placed in a contracted state. The holding enclosure 210,2100 can be considered "unlocked" in its receptive or expanded states, and "locked" in its contracted state, with respect to the nature of the hold that the static trial holder 200,2000 potentially can have or has on the cylindrical trunk 106,1060. Preferably, when the holding enclosure 210,2100 is locked, a force greater than that which is applicable by an unaided surgeon or nurse (i.e., that which can be applied to remove the cylindrical trunk 106,1060 from the holding enclosure 210,2100 when the holding enclosure 210,2100 is in its receptive state), and greater than that which will be experienced by the static trial 100,1000 (or distraction spacer) and the static trial holder 200,2000 during surgical procedures) would be required to pull the cylindrical trunk 106,1060 out of the holding enclosure 210,2100. The placement of the holding enclosure 210,2100 in its locked state or unlocked state is effected by operation of a holding assembly that includes the extension 204,2040 and the sleeve 206,2060 and the manner in which they are configured and interact.

[00113] More particularly, the prongs 214a-b, 2140a-b can be brought together (or brought closer to one another; it should be understood that they need not touch to be encompassed by the present invention), to lock the holding enclosure 210,2100, by a rotation of the sleeve 206,2060 with respect to the handle 202,2020 and the extension 204,2040 about the longitudinal axis of the shaft 208,2080. A rotation control knob 219,2190 is provided to ease the rotation of the sleeve 206,2060. As shown in Figs. 2g and 2i-j in view of Figs. 2d-e and Figs. 2gg and 2ii-jj in view of Figs. 2dd-ee, the bore 218,2180 of the sleeve 206,2060 (shown in cutaway in Figs. 2e and 2ee) defines a cross-section that has a width 220,2200 that is greater than its depth 222,2220. Further as shown in those figures, the prongs 214a-b, 2140a-b when separated (shown in cutaway in Figs. 2j and 2jj) define a cross-section having a width 224,2240

that is greater than its depth 226,2260, the width 224,2240 and depth 226,2260 of the prongs' cross-section being closely accommodated by the width 220,2200 and depth 222,2220 of the bore's cross-section. When the prongs 214a-b,2140a-b are together, the width of prongs' cross-section is closely accommodated by the depth 222,2220 of the bore's cross-section. Thus, when the sleeve 206,2060 is rotated with respect to the extension 204,2040, the sides of the bore defining the depth 222,2220 of its cross-section bear against the sides of the prongs 214a-b,2140a-b defining the width of their cross-section.

[00114] It should be noted that in order to ease the rotation of the sleeve 206,2060 so that the side of the bore 218,2180 can bear against the sides of the prongs 214a-b,2140a-b, the corners of the bore 218,2180 are radiused, and at least the sides (that face away from one another) of the prongs 214a-b,2140a-b are curved. Preferably, as shown, the prongs 214a-b,2140a-b when separated define a partial cylindrical cross-section. The effect of the bearing (of the sides of the bore 218,2180 against the sides of the prongs 214a-b,2140a-b) is borne by the space between the prongs 214a-b,2140a-b, so that the space narrows and the prongs 214a-b,2140a-b are brought toward one another until they are accommodated within the bore's depth 222,2220. The bringing together of the prongs 214a-b,2140a-b brings the semicircular extents 216a-b,2160a-b together to place the holding enclosure 210,2100 into its contracted state, locking it.

[00115] Preferably, with regard to the static trial holder 200, the sleeve 206 is biased toward establishing the holding enclosure 210 in either an unlocked position or a locked position. Stated alternatively, when the holding enclosure 210 is unlocked (or locked), the force required to begin rotation of the sleeve 206 is greater than the force required to continue rotating the sleeve 206 once rotation has begun. And, as the sleeve 206 is rotated toward a position that will unlock (or lock), the holding enclosure 210, it is biased toward stopping its rotation at that upcoming position. Stated alternatively, as the sleeve 206 is being rotated, the force required to rotate the sleeve 206 past that upcoming position is greater than the force that is required to rotate it prior to reaching that upcoming position.

[00116] This biasing of the sleeve 206 of the static trial holder 200 toward positions that will either unlock or lock the holding enclosure 210 is effected by the inclusion of at least one spaced recess 228 on the outer surface of the extension 204, and at least one radial bore 230 through the wall of the sleeve 206 (preferably through the rotation control knob 219 as shown), which bores 230 each have secured therein a spring plunger (not shown) (it should be understood that functionally equivalent devices can also be used in place of a spring plunger).

Preferably, each recess 228 is associated with a respective cooperating bore 230 and spring plunger. When a given bore 230 (and spring plunger) is aligned with its associated recess 228, the sleeve 206 is in a position at which the holding enclosure 210 is either unlocked or locked. Each of the spring plungers is biased radially inwardly from the inner surface of the sleeve 206, and as such presses against the outer surface of the extension 204 as the sleeve 206 is being rotated. Thus, when a recess 230 is presented to the spring plunger, it plunges into the recess 230, stopping the rotation of the sleeve 206. In order to restart (or continue) rotation of the sleeve 206, the bias of the spring plunger must be overcome when the restarting (or continuing) rotational force is applied. In order to lower the overcoming force required to restart or continue the rotation, the end of the spring plunger is preferably convexly curvate, and the recess is concavely curvate. Preferably, four recesses 228 and bores 230 (and spring plungers) are provided, each pair representing one of four quarter-turn rotated positions of the sleeve 206. At each position of the sleeve 206, all four plungers plunge into the recesses 228, securing the sleeve 206 at that position until a sufficient force is applied to overcome their plunging bias.

[00117] Preferably, with regard to the alternate static trial holder 2000, the movement of the sleeve 2060 toward positions that will either unlock or lock the holding enclosure 2100, and the stopping of the sleeve 2060 at such positions, is effected by the inclusion of at least one groove 2280 that extends in a 90 degree arc on the outer surface of the extension 2040, and at least one radial bore 2300 through the wall of the sleeve 2060 (preferably through the rotation control knob 2190 as shown), which bores 2300 each have secured therein a dog headed screw (not shown) so that a head of the screw protrudes into interior of the sleeve (it should be understood that functionally equivalent devices can also be used in place of a dog headed screw). Preferably, each groove 2280 is associated with a respective cooperating bore 2300 and dog headed screw. When a given bore 2300 (and dog headed screw) is aligned with an end of its associated groove 2280, the sleeve 2060 is in a position at which the holding enclosure 2100 is either unlocked or locked (unlocked when the head of the screw is positioned at one end of the groove, locked when it is positioned at the other end of the groove). The head of the dog headed screw protrudes into the interior of the sleeve and into the groove 2280 and rides therein as the sleeve 2060 is rotated. When an end of the groove 2280 is reached by the head of the screw, the head of the screw stops against the wall of the groove 2280 at the end of the groove 2280, stopping the rotation of the sleeve 2060, and setting the holding enclosure 2100 to either the unlocked or locked position. In order to set the holding enclosure 2100 to the alternative position, the sleeve 2060 is reverse rotated,

causing the head of the screw to ride in the groove 2280 in the opposite direction toward the other end of the groove 2280. When the head of the screw reaches the other end of the groove 2280, the head of the screw stops against the wall of the groove 2280 at that end of the groove 2280, stopping the rotation of the sleeve 2060, and setting the holding enclosure 2100 to the alternative position.

[00118] Further, with regard to the alternate static trial holder 2000, the sleeve 2060 preferably has on its exterior surface at least one stop protrusion 1380 that is positioned and dimensioned to extend dorsally or ventrally from the exterior surface when the holding enclosure is in its "locked" state (see Figs. 2ll-qq), so that when the surgeon inserts the static trial 100,1000 into the intervertebral space, the stop protrusions 1380 prevent the static trial 100,1000 from being inserted too far into the space (that is, so that the stop protrusions 1380 hit against the lips of the adjacent vertebral body endplates before the static trial 100,1000 is inserted too far). It should be understood that stop protrusions can be applied to the static trial holder 200 without departing from the scope of the invention.

[00119] Accordingly, the static trials 100,1000 of the invention (or distraction spacers such as those disclosed in the '127 application) can be held and manipulated with either static trial holder 200,2000, and from a variety of approach angles. Holding the handle 202,2020 of the static trial holder 200,2000 in one hand, an operator can push the cylindrical trunk 106,1060 of the static trial 100,1000 (or the distraction spacer) against the mouth 213,2130 of the holding enclosure 210,2100 with enough force to temporarily expand the mouth 213,2130 to a width that will accommodate the diameter of the cylindrical trunk 106,1060 for passage through the mouth 213,2130. The radially inward tapering of the sides of the mouth 213,2130 (the facing ends 215a-b,2150a-b of the semicircular extents 216a-b,2160a-b of the prongs 214a-b,2140a-b) facilitates this insertion. It should be noted that, with regard to the alternate static trial holder 2000, as shown in Figs. 2ll-qq-ff with reference to Figs. 1aa and 2jj, the depth 2260 of the prongs' cross-section is closely accommodated by the depth of the opening establishing by the width of the annular groove 1020 of the alternate static trial 1000 and the depths 1340 of the notches in the pair of opposing notches (1320a,d, 1320b,d, or 1320c,f), and the width 2240 of the prongs' cross-section is accommodated by the width 1360 of the notches in the pair of opposing notches (1320a,d, 1320b,d, or 1320c,f), so that the prongs' cross-section fits into the opposing notches as, and when, the cylindrical trunk 1060 is surrounded by the semicircular extents 2160a-b. (That is, that the width 1360 of the notch pair accommodates the width 2240 of the static trial holder's 2000 prongs' 2140a-b cross-section even when the prongs 2140a-b are

separated to place the holding enclosure 2100 in an expanded state as described below. This enables the notch pair to accommodate the width 2240 of the prongs' cross-section as the cylindrical trunk 1060 of the static trial 1000 is being snapped into the holding enclosure 2100.)

[00120] Once the cylindrical trunk 106,1060 has passed into the holding enclosure

5 210,2100, the operator can let go of the static trial 100,1000 (or distraction spacer) because the prongs 214a-b,2140a-b will be overcome by their bias toward their neutral state and thus hold the static trial 100,1000 in the holding enclosure 210,2100 to prevent the static trial 100,1000 from falling out or slipping out as the static trial holder 200,2000 is moved with the static trial 100,1000 prior to closing (e.g., locking) the holding enclosure 210,2100. (When the static trial
10 100,1000 (or distraction spacer) is being held in this manner, and the holding enclosure 210,2100 is unlocked, the static trial 100,1000 can be removed from the holding enclosure 210,2100 by a pulling of the static trial 100,1000 through the mouth 213,2130 of the holding enclosure 210,2100 with a force required to again temporarily overcome the bias of the prongs 214a-b,2140a-b toward their neutral state, to separate them and make the width of the mouth
15 213,2130 accommodate the diameter of the cylindrical trunk 106,1060.)

[00121] With regard to the static trial holder 200, once the operator is ready to lock the holding enclosure 210, while still gripping the handle 202 of the static trial holder 200, he rotates the rotation control knob 219 either clockwise or counterclockwise to move the sleeve 206 to the next quarter-turn position. If the rotation control knob 219 is rotated with enough force
20 to cause the spring plungers in the bores 230 to back out of the recesses 228, the sleeve 206 will rotate as desired. Once the sleeve 206 has reached the next quarter-turn position, the spring plungers will find the recesses 228 associated with that position, and plunge into the recesses 228 to snap the sleeve 206 into the proper position. As the sleeve 206 rotates, the sides of the sleeve's bore's inner surface bear against the curved outer surfaces of the prongs
25 214a-b to push the prongs 214a-b together so that they are accommodated by the depth 222 of the bore 218. When the prongs 214a-b are pressed against one another and held in that closed position by the maintenance of the sleeve 206 in the new position (maintained by the spring plungers in the recesses 228), the semicircular extents 216a-b move toward one another and are correspondingly maintained together about the cylindrical trunk 106,1060. When the prongs
30 214a-b are held in this manner, the cylindrical trunk 106,1060 cannot be removed through the mouth 213 of the now-tighter (e.g., locked) holding enclosure 210 without the application of forces preferably greater than will be encountered when inserting and removing the static trial 100,1000 from the intervertebral space during the surgical procedures. Once the static trial

100,1000 has been inserted and removed from the intervertebral space (or the distraction spacer has been inserted and removed from the intervertebral space after being used to distract the space), the operator can lock the holding enclosure 210 by rotating the sleeve 206 another quarter turn (in either the clockwise or the counterclockwise direction). Again, if the rotation control knob 219 is rotated with enough force to cause the spring plungers to back out of the recesses 228, the sleeve 206 will rotate as desired. Once the sleeve 206 has reached the next quarter-turn position, the spring plungers will find the recesses 228 associated with that position, and plunge into the recesses 228 to snap the sleeve 206 into the proper position. As the sleeve 206 rotates, the sides of the sleeve's bore's inner surface move away from the curved outer surfaces of the prongs 214a-b and allow the prongs 214a-b to separate (under their own bias toward the neutral position) as they are accommodated by the width 220 of the bore 218. When the prongs 214a-b are separated and allowed to remain in that position by the maintenance of the sleeve 206 in the new position (maintained by the spring plungers in the recesses 228), the semicircular extents 216a-b are separated from one another and hold the cylindrical trunk 106,1060 against falling or slipping out. That is, the cylindrical trunk 106,1060 can be removed by the operator if the operator applies a sufficient force to widen the mouth 213 of the holding enclosure 210 enough to let the cylindrical trunk 106,1060 pass through the mouth 213. Once the static trial 100,1000 (or distraction spacer) is removed, another one can be inserted and manipulated if required.

[00122] With regard to the static trial holder 2000, once the operator is ready to lock the holding enclosure 2100, while still gripping the handle 2020 of the static trial holder 2000, he rotates the rotation control knob 2190 clockwise (or counterclockwise depending on how the grooves 2280 are configured; that is, they are illustrated as being configured to enable a locking with a clockwise rotation, and an unlocking with a subsequent counterclockwise rotation, although other embodiments can enable a locking with a counterclockwise rotation, and an unlocking with a clockwise rotation, to accommodate left-handed persons or right-handed persons or for other reasons) to rotate the sleeve 2060 ninety degrees to the next position. As the sleeve 2060 rotates, the head of the dog headed screw rides freely in the groove 2280, and the sides of the sleeve's bore's inner surface bear against the curved outer surfaces of the prongs 2140a-b to push the prongs 2140a-b together so that they are accommodated by the depth 2220 of the bore 2180. As the dog headed screw reaches the end of the groove 2280, the prongs 2140a-b are pressed against one another and the semicircular extents 2160a-b move toward one another. The prongs 2140a-b are held in and biased toward the closed position, and

the semicircular extents 2160a-b are correspondingly maintained together about the cylindrical trunk 106,1060, by the fitting of the bore's surfaces against the prongs' surfaces. When the prongs 2140a-b are held in this manner, the cylindrical trunk 106,1060 cannot be removed through the mouth 2130 of the now-tighter (e.g., locked) holding enclosure 2100 without the application of forces preferably greater than will be encountered when inserting and removing the static trial 100,1000 from the intervertebral space during the surgical procedures.

[00123] Further with regard to the static trial holder 2000 engaging the static trials 1000, the interference between the prongs 2140a-b and the opposing notches in the notch pair in which the prongs 2140a-b are disposed prevents rotation of the static trial 1000 about a longitudinal axis (e.g., an axis parallel to the longitudinal axis of the cylindrical trunk 1060) with respect to the static trial holder 2000. That is, if the static trial 1000 is encouraged, by forces encountered during manipulation of the static trial 1000, to rotate about such an axis with respect to the static trial holder 2000, the side walls of the notches will be confronted by the prong 2140a-b bodies and such rotational movement of the static trial 1000 will be stopped. (As can be seen in the Figs. 3a-f, the prongs 2140a-b are too deep to fit into the annular groove 1060 without the notch pair accommodating their depth.) The same will happen if a reverse rotation about such an axis is attempted.

[00124] Further with regard to the static trial holder 2000, once the static trial 100,1000 has been inserted and removed from the intervertebral space (or the distraction spacer has been inserted and removed from the intervertebral space after being used to distract the space), the operator can unlock the holding enclosure 2100 by reverse rotating the sleeve 2060 (with enough initial force to overcome the biasing of the fitting of the bore's and the prongs' surfaces) ninety degrees. Again, as the sleeve 2060 rotates, the sides of the sleeve's bore's inner surface move away from the curved outer surfaces of the prongs 2140a-b and allow the prongs 2140a-b to separate (under their own bias toward the neutral position) as they are accommodated by the width 2200 of the bore 2180. When the prongs 2140a-b are separated and allowed to remain in that position by the maintenance of the sleeve 2060 in the new position (with the head of the dog headed screw against the wall of the groove 2280 at the other end of the groove 2280), the semicircular extents 2160a-b are separated from one another and hold the cylindrical trunk 106,1060 against falling or slipping out. That is, the cylindrical trunk 106,1060 can be removed by the operator if the operator applies a sufficient force to widen the mouth 2130 of the holding enclosure 2100 enough to let the cylindrical trunk 106,1060 pass through the mouth 2130. Once the static trial 100,1000 (or distraction spacer) is removed, another one can

be inserted and manipulated if required. As shown in Figs. 200-qq, in addition to the anterior approach angle shown in Figs. 2ll-nn, the illustrated notch configuration accommodates two anterior-lateral approach angles as well.

[00125] Accordingly, the static trial holder 200,2000 can be used to insert and
5 remove the distraction spacers of the '127 application to distract the intervertebral space as described in the '127, and thereafter (or during the distraction) hold to insert and remove the static trials 100,1000 to find the appropriate size of artificial intervertebral disc to be implanted.

[00126] A preferred embodiment of a dynamic trial of the present invention will
now be described.

10 [00127] Referring now to Figs. 3a-d, a dynamic trial of the present invention is shown in top (Fig. 3a), side (Fig. 3b), side cutaway (Fig. 3c) and perspective (Fig. 3d) views.

[00128] The dynamic trial 300 is provided primarily for distracting an intervertebral
space according to the procedures described herein and/or for determining the appropriate size
of an artificial intervertebral disc to be implanted (or whether a particular size can be implanted)
15 into the distracted intervertebral space. While the distraction systems and methods described in
the '127 application, as well as the static trials described herein (e.g., when used in the manner
that the distraction spacers of the '127 application are used), are also useful for distracting an
intervertebral space, the dynamic trial 300 is provided as an additional or alternate distraction
tool. Further, while the static trials described herein are useful for determining the appropriate
20 size of an artificial intervertebral disc to be implanted (or whether a particular size can be
implanted), the dynamic trial 300 is provided as an additional or alternate sizing tool.

[00129] More specifically, the dynamic trial 300 includes a shaft 302 having a
bifurcated trial 304 at a distal end of the shaft 302. The trial 304 has an exterior that is
preferably formed like the artificial intervertebral disc that it is meant to approximate.

25 Accordingly, each half 306a-b of the bifurcated trial 304 has on its outwardly facing surface a
convex dome 308a-b that is shaped like the convex dome of the corresponding baseplate of the
artificial intervertebral disc that the dynamic trial 300 approximates (e.g., the convex domes
184a-b of the baseplates 168a-b of the artificial intervertebral disc 160 of Figs. 1g-n). Preferably,
each convex dome 308a-b is smooth, rather than having a porous coating that is preferred for
30 the convex domes 184a-b of the artificial intervertebral disc 160, and each half 306a-b does not
have stabilizing spikes such as the stabilizing spikes 188a-b on the outwardly facing surfaces
186a-b of the artificial intervertebral disc 160. The omission of these device stabilizing and bone
ingrowth encouraging structures and surfaces on the dynamic trial 300 enables the surgeon to

test the size of the artificial intervertebral disc 160 to be implanted without invading the vertebral body endplates. The shaft 302 includes an inner shaft portion 310 that centrally divides at a fulcrum 311 into upper and lower distal extensions 312a-b. The lower distal extension 312b is fixed to the upper distal extension 312a at the fulcrum 311, preferably by screws 313a-b that are
5 plug welded in place. Preferably, as shown, at least the most proximal screw 313b extends above the top surface of the upper distal extension 312a to serve as a backup stop to prevent extreme forward movement of the control knob 318 that is operated to separate the distal extensions 312a-b (described below).

[00130] From the point of division to their distal ends, each of the upper and lower
10 distal extensions 312a-b are spring biased (preferably by the formation of the fulcrum 311 in combination with the strength of the material of which the extensions 312a-b are made, although the use of other types of springs is contemplated by the present invention) toward positions in which they converge toward one another (in the figures, the extensions 312a-b are shown in these positions). The lower distal extension 312b is connected (preferably fixed as shown) to
15 the lower half 306b of the bifurcated trial 304, and the upper distal extension 312a is connected to the upper half 306a of the bifurcated trial 304. Preferably, as shown, the upper half 306a is adjustably connected to the upper distal extension 312a by a pivot pin 315 that allows the upper half 306a to rotate about a lateral axis that passes through the longitudinal and lateral center of the bifurcated trial 304. This axis of rotation allows the upper half 306a, when separating from
20 the lower half 306b, to adjust to the orientation of the upper (adjacent) vertebral bone without causing the bone to hinge relative to the lower vertebral bone (the bone adjacent the lower half 306b).

[00131] In order to effect the separation of the upper and lower halves 306a-b, the shaft 302 further includes an outer shaft portion 314 that is longitudinally translatable adjacent
25 the inner shaft portion 310. The outer shaft portion 314 preferably straddles the inner shaft portion 310 as shown, and includes a pin 316 that passes between the distal extensions 312a-b. The outer shaft portion 314 is preferably translatable distally by the forward movement of a control knob 318 near the proximal end of the shaft 302, and translatable proximally by
backward movement of the control knob 318. That is, when the control knob 318 is pushed
30 distally, the outer shaft portion 314 moves distally, and accordingly the pin 316 moves distally. If the pushing force is great enough to overcome the bias of the divided extensions 312a-b (their bias toward one another), the divided extensions 312a-b will separate as the pin 316 moves between them (to make room for the pin 316). The separation of the extensions 312a-b

will correspondingly separate the halves 306a-b of the bifurcated trial 304. It should be understood that preferably, if the control knob 318 is released, the bias of the divided extensions 312a-b will press against the pin 316, causing the pin 316 (and correspondingly the outer shaft portion 314 and the control knob 318) to move proximally to allow the divided extensions 312a-b to return to their biased position, which will bring the halves 306a-b of the trial 304 back together so they can be removed from the intervertebral space. Preferably, markings 320 are provided on the inner shaft portion 310 (preferably on its top surface so that the surgeon can more easily see the markings 320) to quantify the depth (to which the bifurcated trial 304 is expanded) corresponding to the distance that the outer shaft portion 314 is translated with respect to the inner shaft portion 310.

[00132] It is anticipated that the pushing force required to separate the halves 306a-b will increase as they separate, due to the compression of the spine seeking to close the intervertebral space and the annulus seeking to prevent the adjacent vertebral discs from separating beyond a certain point. Therefore, to provide a mechanical advantage to the operator in the event that greater distraction is required, but the operator cannot push the control knob 318 farther with unaided human effort, a fine control knob 322 is provided. The fine control knob 322 is preferably threaded onto the proximal end of the inner shaft portion 310, proximal to the control knob 318. Thus, rotation of the fine control knob 322 about the longitudinal axis of the inner shaft portion 310 will cause the body of the fine control knob 322 to press against the control knob 318 to move it farther distally. The interference of the threads of the fine control knob-inner shaft portion interface prevents the fine control knob 322 from backing up proximally unless the fine control knob 322 is reverse rotated to effect that result.

[00133] Preferably, as shown, the proximal end 324 of the shaft 302 is preferably flanged to serve as a slap hammer for impaction (by hitting the proximal end 324 with a mallet with a distally directed force, e.g.), if necessary for proper positioning of the bifurcated trial 304, and/or forced extraction of the bifurcated trial 304 (by hitting the flange of the proximal end 324 with a mallet with a proximally directed force, e.g.).

[00134] Accordingly, the dynamic trial 300 can be used as an additional or alternative distracting tool (e.g., to the distraction spacers), and/or as an alternative or additional sizing tool (e.g., to the static trials). As an example of a use for the dynamic trial 300 as an alternative or additional distraction tool and an alternative sizing tool, once the intervertebral space is distracted to (or, without distraction, is at) a depth that is at least equal to the depth of the closed bifurcated trial 304, the bifurcated trial 304 of the dynamic trial 300 can be inserted

into the intervertebral space. (If the intervertebral space must be distracted initially because it starts out more shallow than the depth of the closed bifurcated trial 304, the distraction spacers of the '127 application and the methods disclosed therein can be used, e.g.) The control knob 318 and/or fine control knob 322 can be operated to separate the halves 306a-b of the bifurcated trial 304 to distract the space as clinically appropriate. Because the bifurcated trial 304 is shaped externally to approximate the artificial intervertebral disc to be implanted (e.g., the artificial intervertebral disc 160), and because the pivoting of the upper half 306a of the bifurcated trial 304 allows the halves 306a-b to appropriately lordotically orient themselves, when the surgeon determines the intervertebral space to be distracted to its proper dimension (based on how much compression is being experienced on the dynamic trial 300 and how tight the annulus is), he can read the markings 320 on the shaft 302 to determine what size of artificial intervertebral disc 160 is suitable for the dimensioned intervertebral space. A subsequent bringing together of the halves 306a-b and a removal of the dynamic trial 300 can then be followed by insertion of the appropriately sized artificial intervertebral disc 160 (e.g., in manners described below with regard to the inserter/impactors).

[00135] As an example of a use for the dynamic trial 300 as an alternative distraction tool and an additional sizing tool, after the surgeon has initially distracted the intervertebral space (preferably with the distraction spacers of the '127 application or the static trials described herein), and applied one or more of the static trials 100,1000 to the intervertebral space to determine the appropriate size of the artificial intervertebral disc to be implanted (e.g., the artificial intervertebral disc 160), the surgeon can apply the dynamic trial 300, expand it to the size of the static trial 100,1000 that was determined to be the appropriate size for the intervertebral space, and then further open the dynamic trial 300 for a final sizing. An example of a final sizing that would be useful would be to test the amount of farther distraction that is clinically possible, without having to remove and replace static trials 100,1000 when the compression force of the spine and the tension force of the annulus are at their higher levels. Also, the surgeon may wish to distract the space slightly more than the size of the appropriately sized static trial 100,1000 or artificial intervertebral disc 160, so that the artificial intervertebral disc 160 can be more easily inserted after removal of the static 100,1000 or dynamic trial 300 results in a compressive settling of the intervertebral space. The surgeon may also wish to distract the space slightly more than the size of the appropriately sized static trial 100,1000 or artificial intervertebral disc 160, to prepare it for easy insertion of the artificial intervertebral disc 160 to be implanted, with consideration for the height of the stabilizing spikes 188a-b on the

outwardly facing surfaces 186a-b of the baseplates 168a-b of the artificial intervertebral disc 160. While the artificial intervertebral disc 160 having the spikes 188a-b can be implanted without the additional distraction, some surgeons may find such additional distraction useful or desirable for a particular case.

5 [00136] Preferred embodiments of inserter/impactors of the present invention will now be described.

 [00137] Referring now to Figs. 4a-d, an inserter/impactor of the present invention is shown in side (Fig. 4a), top (Fig. 4b), side cutaway (Fig. 4c) and perspective (Fig. 4d) views. Figs. 4e-h show side (Fig. 4e), top (Fig. 4f), side cutaway (Fig. 4g), and perspective (Fig. 4h) views of an inserter/impactor of the present invention holding a static trial of the present invention. Figs. 4i-j show top views of an inserter/impactor of the present invention holding a static trial of the present invention in two alternative ways. Figs. 4k-n show side (Fig. 4k), top (Fig. 4l), side cutaway (Fig. 4m), and perspective (Fig. 4n) views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention. Figs. 4o-p show top views of an inserter/impactor of the present invention holding an exemplary artificial intervertebral disc of the present invention in two alternative ways.

 [00138] Referring now to Figs. 4aa-ll, Figs. 4aa-cc side (Fig. 4aa), perspective (Fig. 4bb), and close-up perspective (Fig. 4cc) views of a wedge plate inserter/impactor of the present invention. Figs. 4dd-gg show bottom (Fig. 4dd), side (Fig. 4ee), top (Fig. 4ff), and side cutaway (Fig. 4gg) views of a distal end of a wedge plate inserter/impactor of the present invention. Figs. 4hh-ii show top (Fig. 4hh) and side (Fig. 4ii) views of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc. Figs. 4jj-ll show top (Fig. 4jj), side (Fig. 4kk), and side cutaway (Fig. 4ll) views of a distal end of a wedge plate inserter/impactor of the present invention holding an exemplary artificial intervertebral disc.

 [00139] Each inserter/impactor 400,4000 is provided primarily for holding, inserting, repositioning, removing, impacting, extracting, and otherwise manipulating an artificial intervertebral disc having features suitable for being manipulated by the inserter/impactor. (However, they can also be used to hold, insert, reposition, remove, impact, extract, and otherwise manipulate the static trials 100,1000 as described above, as well as any other orthopedic device having suitable features therefor. For example, it should be understood that distraction of an intervertebral space can be accomplished in conjunction with a cooperating tool or spacer that can be gripped by the inserter/impactor.) Exemplary suitable artificial

intervertebral discs include, but are not limited to, the artificial intervertebral disc 160 described herein and the artificial intervertebral discs described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by the inserter/impactor 400,4000, such features include those discussed above as being suitable features on the static trials 100,1000 and disc 160, namely, an anteriorly facing flat surface on the second (e.g., lower) baseplate of the trial or disc, flanked by two anteriolaterally facing flat surfaces (one on each side of the anteriorly facing flat surface), and, to provide for holding of the trial or disc for an anterior insertion approach, a hole spaced from the anteriorly facing flat surface, the hole having a longitudinal axis parallel to the anteriorly facing flat surface. Further regarding the features suitable for being manipulated by the wedge plate inserter/impactor 4000, such features further include the inwardly facing surfaces of the baseplates of the trial or disc.

[00140] More particularly, the inserter/impactor 400,4000 includes a shaft 402,4020 having a distal end 404,4040 that has angled flat surfaces 420a-c,4200a-f corresponding to and fittable against angled flat surfaces of the static trial (e.g., the surfaces 120a-f,1200a-f of the static trial 100,1000) or artificial intervertebral disc (e.g., the surfaces 180a-f of the artificial intervertebral disc 160) to be implanted. For example, in an anterior approach for the trial 100,1000 (as shown in Figs. 4e-h as an example of how either static trial 100,10000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420a (or 4200a and 4200d), 120b,1200b and 120e,1200e facing 420b (or 4200b and 4200e), and 120c,1200c and 120f,1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in Figs. 4k-n as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420a (or 4200a and 4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (4200c and 4200f). Additionally with regard to the wedge plate inserter/impactor 4000, the distal end 4040 has a wedge-shaped extension 4042 including upper 4200g and lower 4200h wedge surfaces corresponding to and fittable against the inwardly facing surfaces of the artificial intervertebral disc (e.g., the lower surface 164a of the upper baseplate 168a of the disc 160, and the upper surface 164b of the lower baseplate 168b of the disc 160, respectively) to be implanted, causing the baseplates to be angled at a 15 degree lordosis angle, with the lower surface 164a of the

upper baseplate 168a held against the upper surface 4200g, and the upper surface of the shield being held against the lower surface 4200h, as best shown in Figs. 4hh-II.

[00141] In particular with regard to the wedge plate inserter/impactor 4000, the inserter/impactor 4000 holds the disc 160 in a preferred position with respect to the
5 inserter/impactor 4000. (It should be understood that the surfaces of the wedge-shaped extension 4042 can be modified within the scope of the present invention to hold the disc 160 (or another orthopedic device) at positions other than those illustrated herein.) In the illustrated embodiment of the inserter/impactor 4000 in use with the disc 160, the preferred position is with the baseplates 168a,b of the disc 160 angle at 15 degrees of lordosis with respect to one
10 another. More particularly, as best shown in Figs. 4hh-II, preferably, the upper and lower surfaces (e.g., 4200g and 4200h) of the wedge-shaped extension 4042 protrude from the distal end 4040 and are formed to hold the baseplates 168a,b such that they are angled at 15 degrees of lordosis with respect to one another. A surface (e.g., lower surface 4200h) of the wedge-shape extension 4042 that mates with an inwardly facing surface of a baseplate (e.g., the lower
15 baseplate 168b) of a disc (e.g., 160) may be correspondingly shaped (e.g., curved or flat) for interaction or mating with the disc baseplate (e.g., the lower surface 4200h of the wedge-shaped extension as illustrated is curved to accommodate the surface of the shield of the disc). Preferably, the forward surface 4200i of the wedge-shaped extension 4042 has a concave curvature towards the shaft 4020 of the inserter/impactor 4000, also for accommodating the
20 curvature of the surface of the shield of the disc.

[00142] Also preferably with regard to the wedge plate inserter/impactor 4000 and this preferred positioning, the wedge surfaces of the distal end 4040 protrude from a distance midway with respect to the top and bottom of the distal end 4040 and span (e.g., right to left or vice-versa) the entire distal face of the distal end 4040, and the surfaces 4200d-f above the
25 wedge on the distal end 4040 are respectively perpendicular to the wedge's upper surface 4200g such that each is disposed in parallel with its respective corresponding surface of the disc 160 when the disc 160 is held by the inserter/impactor 4000 at the appropriate lordosis angle. (And, accordingly, are angled approximately 15 degrees with respect to the surfaces below the wedge 4200a-c.) Preferably, for an anterior approach, the wedge-shaped extension 4042 is
30 designed and shaped to fit with its antero-lateral confronting surfaces (4200d,f and 4200a,c) tightly against the correspondingly antero-laterally facing surfaces (180d,f and 180a,c) of the disc 160, but such that its anterior confronting surfaces (4200e and 4200b) are slightly spaced from the anteriorly facing surfaces (180d and 180b) of the disc 160, when the disc is held by the

5 inserter/impactor 4000. This is primarily to address manufacturing issues (in some instances, tolerances may not be adequately defined to ensure that all of those surfaces fit tightly against their corresponding surfaces), so that if there are manufacturing anomalies, any slight tolerance differences that may exist are nevertheless still adequate to ensure at least the tight fitting of the antero-lateral confronting surfaces, so that manipulation of the disc 160 is possible (e.g., in the manner of a wrench against an angled nut). This can be achieved, e.g., by designing the anterior confronting surfaces (4200e and 4200b) to each be slightly greater in length than the corresponding anteriorly facing surfaces (180e and 180b) of the disc baseplates, while still being angled with respect to the antero-lateral confronting surfaces (4200d,f and 4200a,c) at the same angle the antero-laterally facing surfaces (180d,f and 180a,c) of the disc baseplates are angled with respect to the anteriorly facing surfaces (180e and 180b) of the disc. The increased length of the anterior confronting surfaces on the wedge extension results in the slight clearance between the anteriorly facing surfaces (180e and 180b) of the disc and the corresponding anterior confronting surface (4200e and 4200b) of the wedged distal end, thereby ensuring that the disc will be fully seated against the antero-lateral confronting surfaces of the distal end despite possible manufacturing, material or other inevitable variations in tolerances of the artificial intervertebral disc or the inserter/impactor. As noted above, similar in this regard to the manner in which a wrench engages a nut, this fitting increases the mechanical advantage toward repositioning the disc in the intervertebral space. It should be noted, inasmuch as the inserter/impactor 4000 described herein can engage the disc from the antero-lateral angles as well, the anterior confronting surfaces (4200e and 4200b) should also be longer than the antero-laterally facing surfaces (180d,f and 180a,c) of the disc, so that a similar fitting occurs when the disc is held from the antero-lateral angles. Stated broadly, the primary confronting surfaces (e.g., the anterior confronting surfaces) of the inserter/impactor are preferably slightly longer than the primary confronted surfaces (e.g., anteriorly facing surfaces) of the disc for any given holding orientation.

[00143] Each inserter/impactor 400,4000 includes a holding pin 408,4080 that extends from the center flat surface 420b,4200b along a longitudinal axis of the shaft 402,4020, the pin 408,4080 having a distal end 410,4100 that is bent downwardly. The holding pin 408,4080 is spring loaded (by a spring 409,4090) in a central channel of the shaft 402,4020, so that it is biased toward and against the shaft 402,4020 (preferably, the bent end 410,4100 of the pin 408,4080 prevents it from entering the central channel). With regard to the wedge plate inserter/impactor 4000, the holding pin 4080 is restricted from upwardly lateral movement with

respect to the distal end of the inserter/impactor 4000 by the presence of the wedge-shaped extension 4042 of the distal end 4040 of the inserter/impactor 4000. More particularly, with any attempted upward movement of the holding pin 4080, the pin encounters the upper surface of the channel in which the pin 4080 travels, preventing any such upward movement. On both
 5 inserter/impactors 400,4000, the holding pin 408,4080 is preferably heat treated (e.g., cold formed) to increase material quality (e.g., strength).

[00144] A flange 411,4110, mechanically connected to the pin 408,4080 and translating adjacent the shaft 402,4020, can be pushed distally to overcome the bias of the spring 409,4090 to space the pin 408,4080 away from the central flat surface 420b,4200b. (An
 10 alternative configuration is one in which the flange 411,4110 and the pin 408,4080 are formed from a single piece, rather than being mechanically connected.) In this extended position, the pin 408,4080 can be inserted in the hole 122b,1220b,182b in the baseplate 108b,1080b,168b of the static trial 100,1000 or artificial intervertebral disc 160. Releasing the flange 411,4110 allows the spring 409,4090 to pull the pin 408,4080 back, causing the anteriorly facing surface
 15 120b,1200b,180b of the baseplate 108b,1080b,168b to be held against the central flat surface 420b of the inserter/impactor 400 (or against the lower central flat surface 4200b of the inserter/impactor 4000) and the anterioplaterally facing flat surfaces 120a,c,1200a,c,180a,c of the static trial 100,1000 or artificial intervertebral disc 160 to be held against the other
 20 corresponding flat surfaces 420a,c of the inserter/impactor 400 (or against the other corresponding flat surfaces 4200a,c of the inserter/impactor 4000). Further and simultaneously, with regard to the wedge plate inserter/impactor 4000, the anteriorly facing surface 180e of the baseplate 168a is pulled against the upper central flat surface 4200e of the inserter/impactor 4000 and the anterioplaterally facing flat surfaces 180d,f of the artificial intervertebral disc 160 is pulled against the other corresponding flat surfaces 4200d,f of the inserter/impactor 4000.
 25 Additionally with regard to the wedge plate inserter/impactor 4000, as noted above, the upper and lower wedge surfaces (4200g,h) interfere between the inwardly facing surfaces 164a,b of the disc baseplates, causing the baseplates to be angled at a 15 degree lordosis angle, with the lower surface 164a of the upper baseplate 168a held against the upper surface 4200g, and the upper surface of the shield being held against the lower surface 4200h, as best shown in Figs.
 30 4hh-II.

[00145] A knob 412,4120, threaded on the shaft 402,4020, can be rotated about the longitudinal axis of the shaft 402,4020 to push the flange 411,4110 farther proximally, to pull the pin 409,4090 tighter and therefore lock its position (the interference of the threads of the

knob-shaft interface prevents the knob 412,4120 from moving distally unless the knob 412,4120 is reverse rotated to effect that result) to more securely hold the baseplate 108b,1080b,168b, and reverse rotated to unlock and loosen the pin 409,4090.

[00146] When the static trial 100,1000 or disc 160 is held in this manner, rotation
 5 of the static trial 100,1000 or disc 160 about a longitudinal axis (of the static trial 100,1000 or disc 160) relative to the inserter/impactor 400,4000 is prevented by interference of the corners of the static trial's 100,1000 or disc's 160 flat surfaces 120a-c,1200a-c,180a-c and the corners of the inserter/impactor's 400,4000 flat surfaces 420a-c,4200a-f, similar to the manner in which a wrench holding a nut prevents rotation of the nut relative to the wrench. Further, the holding of
 10 the static trial 100,1000 or disc 160 in this manner allows for some repositioning of the static trial 100,1000 or disc 160 in the intervertebral space via rotation of the static trial 100,1000 or disc 160 in either direction about the longitudinal axis of the intervertebral space.

[00147] Further, with regard to the wedge plate inserter/impactor 4000, when the
 15 static trial 100,1000 or disc 160 is held in this manner, rotation of the static trial 100,1000 or disc 160 about a lateral axis (of the static trial 100,1000 or disc 160) relative to the inserter/impactor 4000 is prevented by interference of the inwardly facing surface (e.g., 164a) of the first baseplate (e.g., upper baseplate) of the static trial 100,1000 or disc 160 and the upper surface 4200g of the wedge on the distal end 4040, and by interference of the inwardly facing surface (e.g., 164b) of the second baseplate (e.g., lower baseplate) of the static trial 100,1000 or disc 160 and the
 20 lower surface 4200h of the wedge on the distal end 4040. Accordingly, the holding of the static trial 100,1000 or disc 160 in this manner allows for some repositioning of the static trial 100,1000 or disc 160 in the intervertebral space via rotation of the static trial 100,1000 or disc 160 in either direction about the longitudinal or latitudinal axis of the intervertebral space.

[00148] In some embodiments of the wedge plate inserter/impactor 4000, when
 25 the artificial intervertebral disc 160 is held by the inserter/impactor 4000, the flat surfaces 180a-c are more closely confronted by the angled flat surfaces 4200a-c of the inserter/impactor 4000, compared with the flat surfaces 180d-f being less closely confronted by the angled flat surfaces 4200d-f of the inserter/impactor 4000. As such, the structure of the artificial intervertebral disc 160 having the flat surfaces 180d-f (e.g., the upper baseplate 168a) has slightly more rotation
 30 and angulation freedom relative to the inserter/impactor 4000 when being held, compared to the structure of the artificial intervertebral disc 160 having the flat surfaces 180a-c (e.g., the lower baseplate 168b). This permits the artificial intervertebral disc 160 to adjust to the intervertebral space (e.g., to the angulation of the adjacent vertebral endplates, defining the intervertebral

space, relative to one another) as it is being inserted thereinto. That is, typically, the adjacent vertebral endplates will be lordotically angled with respect to one another as a result of the intervertebral space being prepared and distracted.

[00149] Preferably, both of the baseplates of the static trial 100,1000 or disc 160 have similarly configured flat surfaces. For example, the lower baseplate's 108b,1080b,168b flat surfaces 120a-c,1200a-c,180a-c have similarly configured and similarly oriented counterpart flat surfaces 120d-f,1200d-f,180d-f on the upper baseplate 108a,1080a,168a. Further preferably, both baseplates' 108a-b,1080a-b,168a-b flat surfaces 120a-f,1200a-f,180a-f face the angled flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 when the static trial 100,1000 or disc 160 is held by the inserter/impactor 400,4000. For example, in an anterior approach for the trial 100,1000 (as shown in Figs. 4e-h as an example of how either trial 100,1000 can be held by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420a (or 4200a and 4200d), 120b,1200b and 120e,1200e facing 420b (or 4200b and 4200e), and 120c,1200c and 120f,1200f facing 420c (or 4200c and 4200f), and in an anterior approach for the disc 160 (as shown in Figs. 4k-n), 180a and 180d facing 420a (or 4200a and 4200d), 180b and 180e facing 420b (or 4200b and 4200e), and 180c and 180f facing 420c (or 4200c and 4200f).

[00150] It should be noted that preferably, when the static trial 100,1000 is held by the inserter/impactor 400,4000, the flat surfaces 120a-c,1200a-c and the counterpart flat surfaces 120d-f,1200d-f are tightly held against the angled flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 as described above. It is also preferable that the baseplates 108a-b,1080a-b of each of the plurality of static trials 100,1000 be appropriately lordotically angled relative to one another to ease insertion of the static trial 100,1000 into the intervertebral space and to mimic how the artificial intervertebral disc 160 will typically be oriented as it is being inserted using the inserter/impactor 400,4000. While not shown in Figs. 1a-f or Figs. 1aa-ff, in some embodiments, when the static trials 100,1000 are formed in such a lordotically oriented configuration, it is preferable that the flat surfaces 120d-f,1200d-f on the first (e.g., upper) baseplate 108a,1080a be parallel to the flat surfaces 120a-c,1200a-c of the second (e.g., lower) baseplate 108b,1080b in the static trial's 100,1000 appropriately lordotically oriented configuration, so that when the static trial 100,1000 is held tightly by the inserter/impactor 400,4000, the flat surfaces 120a-f,1200a-f are flush with the flat surfaces 420a-c,4200a-f of the inserter/impactor 400,4000 even though the baseplates 108a-b,1080a-b are lordotically angled with respect to one another.

[00151] With regard to the inserter/impactor 400, by contrast, preferably, when the artificial intervertebral disc 160 is held by the inserter/impactor 400, the flat surfaces 180a-c are tightly held against the angled flat surfaces 420a-c of the inserter/impactor 400 as described above, but the counterpart flat surfaces 180d-f are loosely held against the angled flat surfaces 420a-c of the inserter/impactor 400. As such, the structure of the artificial intervertebral disc 160 having the counterpart flat surfaces 180d-f (e.g., the upper baseplate 168a) is able to angulate and rotate to a limited extent relative to the structure of the artificial intervertebral disc 160 having the flat surfaces 180a-c. This permits the artificial intervertebral disc 160 to adjust to the intervertebral space (e.g., to the angulation of the adjacent vertebral endplates, defining the intervertebral space, relative to one another) as it is being inserted thereinto. That is, typically, the adjacent vertebral endplates will be lordotically angled with respect to one another as a result of the intervertebral space being prepared and distracted. As the artificial intervertebral disc 160 is then inserted into the intervertebral space using the inserter/impactor 400, then, the baseplates 168a-b will be permitted to lordotically angle with respect to one another to squeeze into the intervertebral space.

[00152] With regard to the wedge plate inserter/impactor 4000, when the artificial intervertebral disc 160 is held by the inserter/impactor 4000, the wedge surfaces of the distal end 4040 protrude from a distance midway with respect to the top and bottom of the distal end 4040 and span (e.g., right to left or vice-versa) the entire distal face of the distal end 4040, and the surfaces 4200d-f above the wedge on the distal end 4040 are respectively perpendicular to the wedge's upper surface 4200g such that each is disposed in parallel with its respective corresponding surface of the disc 160 when the disc 160 is held by the inserter/impactor 4000 at the appropriate lordosis angle. (And, accordingly, are angled approximately 15 degrees with respect to the surfaces below the wedge 4200a-c.) Preferably, for an anterior approach, the wedge-shaped extension 4042 is designed and shaped to fit with its antero-lateral confronting surfaces (4200d,f and 4200a,c) tightly against the correspondingly antero-laterally facing surfaces (180d,f and 180a,c) of the disc 160, but such that its anterior confronting surfaces (4200e and 4200b) are slightly spaced from the anteriorly facing surfaces (180d and 180b) of the disc 160, when the disc is held by the inserter/impactor 4000. This is primarily to address manufacturing issues (in some instances, tolerances may not be adequately defined to ensure that all of those surfaces fit tightly against their corresponding surfaces), so that if there are manufacturing anomalies, any slight tolerance differences that may exist are nevertheless still adequate to ensure at least the tight fitting of the antero-lateral confronting surfaces, so that

manipulation of the disc 160 is possible (e.g., in the manner of a wrench against an angled nut).

This can be achieved, e.g., by designing the anterior confronting surfaces (4200e and 4200b) to each be slightly greater in length than the corresponding anteriorly facing surfaces (180e and 180b) of the disc baseplates, while still being angled with respect to the antero-lateral

5 confronting surfaces (4200d,f and 4200a,c) at the same angle the antero-laterally facing surfaces (180d,f and 180a,c) of the disc baseplates are angled with respect to the anteriorly facing surfaces (180e and 180b) of the disc. The increased length of the anterior confronting surfaces on the wedge extension results in the slight clearance between the anteriorly facing surfaces (180e and 180b) of the disc and the corresponding anterior confronting surface (4200e and 4200b) of the wedged distal end, thereby ensuring that the disc will be fully seated against the antero-lateral confronting surfaces of the distal end despite possible manufacturing, material or other inevitable variations in tolerances of the artificial intervertebral disc or the

10 inserter/impactor. As noted above, similar in this regard to the manner in which a wrench engages a nut, this fitting increases the mechanical advantage toward repositioning the disc in the intervertebral space. It should be noted, inasmuch as the inserter/impactor 4000 described herein can engage the disc from the antero-lateral angles as well, the anterior confronting surfaces (4200e and 4200b) should also be longer than the antero-laterally facing surfaces (180d,f and 180a,c) of the disc, so that a similar fitting occurs when the disc is held from the antero-lateral angles. Stated broadly, the primary confronting surfaces (e.g., the anterior confronting surfaces) of the inserter/impactor are preferably slightly longer than the primary confronted surfaces (e.g., anteriorly facing surfaces) of the disc for any given holding orientation.

15 [00153] Also preferably, in order to provide for a holding of the static trial 100,1000 or disc 160 for two additional (here, anteriolateral) insertion approaches, each static trial 100,1000 or disc 160 also includes two additional holes 122a,1220a,182a and 122c,1220c,182c, one (e.g., 122a,1220a,182a) spaced apart from one of the anteriolaterally facing flat surfaces (e.g., 120a,1200a,180a), and the other (e.g., 122c,1220c,182c) spaced apart from the other of the anteriolaterally facing flat surfaces (e.g., 120c,1200c,180c). Accordingly, operation of the inserter/impactor 400,4000 can fit the holding pin 408,4080 into either of these two additional holes 122a,1220a,182a or 122c,1220c,182c, and hold the associated anteriolaterally facing flat surface (the one associated with the hole into which the pin 408,4080 is fit) of the static trial 25 100,1000 or disc 160 against the flat surface of the inserter/impactor 400,4000 opposite the pin 408,4080. For example, in a first anteriolateral approach for the trial 100,1000 (as shown in Fig. 4i as an example of how either trial 100,1000 can be engaged by either inserter/impactor

400,4000), 120a,1200a and 120d,1200d not confronted, 120b,1200b and 120e,1200e facing 420a (or 4200a and 4200d), and 120c,1200c and 120f,1200f facing 420b (or 4200b and 4200e), and a first anteriolateral approach for the disc 160 (as shown in Fig. 4o as an example of the how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d not
5 confronted, 180b and 180e facing 420a (or 4200a and 4200d), and 180c and 180f facing 420b (or 4200b and 4200e). And, for example, in a second anteriolateral approach for the trial 100 (as shown in Fig. 4j as an example of how either trial 100,1000 can be engaged by either inserter/impactor 400,4000), 120a,1200a and 120d,1200d facing 420b (or 4200b and 4200e), 120b,1200b and 120e,1200e facing 420c (or 4200c and 4200f), and 120c,1200c and 120f,1200f
10 not confronted, and a second anteriolateral approach for the disc 160 (as shown in Fig. 4p as an example of how the disc 160 can be engaged by either inserter/impactor 400,4000), 180a and 180d facing 420b (or 4200b and 4200e), 180b and 180e facing 420c (or 4200c and 4200f), and 180c and 180f not confronted.

[00154] It should be understood that preferably, in order to facilitate these
15 additional approaches, the angle separating the anteriorly facing flat surface of the static trial 100,1000 or disc 160 and one of the anteriolaterally facing flat surfaces of the static trial 100,1000 or disc 160 is equal to the angle separating the anteriorly facing flat surface and the other of the anteriolaterally facing flat surfaces. Preferably, the surfaces are angled with respect to one another at an angle of 33.4 degrees.

[00155] It should also be understood that the inclusion of additional adjacent
20 angulated surfaces (or placing the angulated surfaces in other locations on the trial or disc or other orthopedic device), and/or including corresponding holes adjacent to such surfaces, can provide the surgeon with additional approaches, e.g., other anteriolateral approaches, directly lateral approaches, posteriolateral approaches, and/or directly posterior approaches. For
25 example, a trial or disc can have angled surfaces (and corresponding holes) along the entire perimeter of one or both of the baseplates, and thus enable the surgeon to engage the trial or disc from a number of angles, including anterior, posterior, lateral, anteriolateral, and posteriolateral angles.

[00156] The inserter/impactor 400,4000 further includes at a proximal end a cap
30 414,4140 for use as an impact surface if the trial 100,1000 or disc 160 must be impacted further into the intervertebral space after insertion, or forcibly extracted from the intervertebral space. A mallet can be used to strike the cap 414,4140 (in a distal direction for impaction, or in a proximal direction (using the flange of the cap 414,4140) for extraction). It should be noted a striking of

the cap 414,4140 will translate the striking force to the baseplates through the shaft 402,4020 and the flat surfaces, but will not damage the holding pin 408,4080 because the holding pin 408,4080 is spring loaded in the central channel and thus buffered from the striking force thereby. The distal end 404,4040 of the inserter/impactor 400,4000 further preferably includes at least one vertebral body stop (e.g., 4202) that protrudes longitudinally with respect to the shaft 402,4020, from the surfaces of the distal end. The stops help prevent the inserter/impactor from being used to insert the disc (or other orthopedic device) too far into the intervertebral space.

[00157] Accordingly, the inserter/impactor 400,4000 can be used to grip either the static trials or the artificial intervertebral disc to be implanted, and hold the same during insertion and/or removal of the same, and is useful for a variety of surgical approach angles.

[00158] Preferred embodiments of a repositioner/extractor of the present invention will now be described.

[00159] Referring now to Figs. 5a-c, a symmetric repositioner/extractor of the present invention is shown in side (Fig. 5a), top (Fig. 5b), and perspective (Fig. 5c) views. And referring now to Figs. 5d-f, an offset left repositioner/extractor of the present invention is shown in side (Fig. 5d), top (Fig. 5e), and perspective (Fig. 5f) views. And referring now to Figs. 5g-i, an offset right repositioner/extractor of the present invention is shown in side (Fig. 5g), top (Fig. 5h), and perspective (Fig. 5i) views. And referring now to Figs. 5j-l, an alternative offset left repositioner/extractor of the present invention is shown in side (Fig. 5j), top (Fig. 5k), and perspective (Fig. 5l) views. And referring now to Figs. 5m-o, an alternative offset right repositioner/extractor of the present invention is shown in side (Fig. 5m), top (Fig. 5n), and perspective (Fig. 5o) views.

[00160] Each repositioner/extractor is provided primarily for repositioning and/or extracting a static trial or artificial intervertebral disc having features suitable for being manipulated by the repositioner/extractor. Exemplary suitable artificial intervertebral discs are described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by each repositioner/extractor, such features include at least two holes extending longitudinally into one of the baseplates of the static trial or artificial intervertebral disc from the inwardly facing surface of the baseplate. More than two holes can be used to provide for multiple repositioning/extracting approaches. Preferably, in order for the same repositioning/extracting tool to be used for multiple approaches

on the same trial or artificial intervertebral disc, adjacent holes should be separated by the same distance separating other adjacent holes.

[00161] In order to engage the two holes, each repositioner/extractor has two pins extending in parallel from a central shaft, perpendicular to the longitudinal axis of the central shaft. The pins are spaced to engage the two holes simultaneously, and each pin has a diameter smaller than the diameter of the hole it is to engage. Therefore, the pins can be inserted into the holes, and pulling or pushing on the central shaft along its longitudinal axis when the holes are engaged pulls or pushes the static trial or artificial intervertebral disc in the intervertebral space. Further, because two holes are engaged, the static trial or artificial intervertebral disc can be rotated in either direction about a longitudinal axis passing through the intervertebral space, by rotating of the central shaft of the repositioner/extractor about its distal end, about an axis parallel to the longitudinal axes of the pins. A handle at a proximal end of the central shaft is useful for pushing or pulling on the shaft. A flange adjacent the proximal end of the shaft is useful for impaction (either with a distally directed force or a proximally directed force), if necessary to manipulate the shaft.

[00162] On each repositioner/extractor, the pins are formed on prongs that extend laterally from the central shaft. The direction of the prongs, and the location of the pins relative to the central shaft, determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Further, the number and location of holes further determine the angle or angles of surgical approach for which a particular repositioner/extractor can be used. Accordingly, the present invention contemplates a variety of repositioner/extractors, and a variety of holes configurations, to provide the surgeon with a variety of possible surgical approach angles.

[00163] For example, three repositioner/extractors are illustrated, and, for example, two hole configurations are illustrated.

[00164] The first, symmetric, repositioner/extractor 500, shown in Figs. 5a-c, includes a shaft 502 having a distal end that is symmetrically divided into two prongs 504a-b, each of the prongs having a pin 506a-b extending upwardly and parallel to the pin on the other prong. The second and third, left offset and right offset, repositioners/extractors 510,520, shown in Figs. 5d-f and 5g-i, respectively, each include a shaft 512,522 having a distal end that bends diagonally laterally, the left offset distal end 514 bending in one direction (e.g., to the left), the right offset distal end 524 bending in an opposite direction (e.g., to the right). The distal end of each of the second and third repositioners/extractors 510,520 has two pins 516a-b,526a-b

serially spaced on the bent portion, and each of the pins extends upwardly and parallel to the other pin. (As shown in Figs. 5j-l and 5m-o, alternative embodiments 530,540 of the second and third, left offset and right offset, repositioners/extractors each include a shaft 532,542 having a distal end that has a straight prong 534a,544a and a curved lateral prong 534b,544b, where the curved lateral prong 534b extends in one direction (e.g., left) for the alternative left offset repositioner/extractor 530, and where the curved lateral prong 544b extends in an opposite direction (e.g., right) for the alternative right offset repositioner/extractor 540. Each of the prongs 534a-b,544a-b has a pin 536a-b,546a-b extending upwardly and parallel to the pin on the other prong. The alternative repositioners/extractors 530,540, each having a space between the pins 536a,b,546a,b, provides for avoidance of any structures on the static trial or artificial intervertebral disc that may be present between the holes.) On each of the repositioners/extractors 500,510,520,530,540, the pins are spaced so that they simultaneously each fit into a respective one of the two adjacent holes in the baseplate of the static trial or artificial intervertebral disc. Each of the repositioners/extractors 500,510,520,530,540 has a handle 508,518,528,538,548 at a proximal end of the central shaft which is useful for pushing or pulling on the shaft, and a flange 509,519,529,539,549 adjacent the proximal end of the shaft that is useful for impaction (either with a distally directed force or a proximally directed force), if necessary to manipulate the shaft.

[00165] As noted above, the repositioner/extractor that is appropriate or desired for a given case depends at least in part on the configuration of the holes in the baseplates. Two hole configurations are disclosed, as examples of suitable configurations, although other configurations are possible and contemplated by the present invention. A first hole configuration includes three holes on one of the baseplates, the holes being configured so that a first hole is located in the anterior-posterior plane, and the adjacent (second and third) holes are located in respective opposing anteriolateral planes on either side of the first hole. This hole configuration is shown in Figs. 5p-u, each of which shows a top cutaway view of the artificial intervertebral disc of Figs. 1g-n, showing its lower baseplate, having the first hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the lower baseplate shows the first hole 550, the second hole 552, and the third hole 554 of the first hole configuration.

[00166] A second hole configuration includes four holes on one of the baseplates, the holes being configured so that first and second holes straddle the anterior-posterior plane, a third hole is located so that the third hole and the first hole straddle one of the opposing anteriolateral planes, and a fourth hole is located so that the fourth hole and the second hole

straddle the other of the opposing anteriolateral planes. This hole configuration is shown in Figs. 5v-dd, each of which shows a bottom cutaway view of the artificial intervertebral disc of Figs. 1g-n, showing its upper baseplate, having the second hole configuration, engaged by one of the repositioners/extractors 500,510,520. Each view of the upper baseplate shows the first hole 560, the second hole 562, the third hole 564, and the fourth hole 566, of the second hole configuration.

[00167] It should be understood that configurations having more or fewer holes, and in a variety of locations, are contemplated by the invention, and the detailed descriptions of only two hole configurations is not meant to limit the invention to only these two configurations. Importantly, the invention encompasses using a hole or any number of holes, bored at any suitable angle, whether parallel to other holes or not, in any number of locations on a spacer, a trial or an artificial intervertebral disc (not limited to locations on the baseplates), for purposes of enabling the spacer, trial, or disc to be engaged by a manipulation instrument (not limited to a repositioner/extractor) that engages the hole, and/or to enable the surgeon to work from a variety of approaches. For example, as described in more detail below, the first and second hole configurations described herein, in cooperation with the repositioner/extractors, provide the surgeon with the ability to work from a directly anterior approach, as well as several anteriolateral approaches. It should be understood that additional hole configurations can enable the surgeon to work from a directly posterior approach, posteriolateral approaches, directly lateral approaches, or anteriolateral approaches that are different than those illustrated. For example, the placement of one or more suitably spaced holes (or the addition of one or more holes) on the posterior edge, and/or one or both of the lateral edges of one or both of the baseplates, would enable the surgeon to use the repositioner/extractors of the present invention to achieve such approaches.

[00168] As noted above, and referring now to Figs. 5p-dd, it can be seen that each of the repositioner/extractors can be used in more than one manner depending on the tool desired and the approach desired. For example, with reference to Figs. 5p-q, regarding the first hole configuration (three holes in one of the baseplates), the symmetric repositioner/extractor 500 can be used in either of two anteriolateral approaches (see Figs. 5p-q). That is, the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from either of the two anteriolateral approaches, and the pins 506a-b can be inserted into the first 550 and second 552 holes (for one of the two anteriolateral approaches) (Fig. 5p) or the first 550 and third 552 holes (for the other of the two anteriolateral approaches) (Fig. 5q) of the first hole configuration.

[00169] Also, for example, with reference to Figs. 5r-u, regarding the first hole configuration, each of the left offset repositioner/extractor 510 and the right offset repositioner/extractor 520 can be used in either a directly anterior approach (Figs. 5r,t) or a respective anteriolateral approach (Figs. 5s,u). That is, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from a direct anterior approach, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 550 and second 552 holes of the first hole configuration (Fig. 5r). And, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from an anteriolateral approach, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 550 and third 554 holes of the first hole configuration (Fig. 5s). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from a direct anterior approach, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 550 and third 554 holes of the first hole configuration (Fig. 5t). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from an anteriolateral approach, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 550 and second 552 holes of the first hole configuration (Fig. 5u). It should be noted that the alternate left offset 530 and alternate right offset 540 repositioners/extractors can also fit into the holes of the first hole configuration in the same manner as described here with regard to the left offset 510 and right offset 520 repositioners/extractors.

[00170] Also, for example, with reference to Figs. 5v-dd, regarding the second hole configuration (four holes in one of the baseplates), the symmetric repositioner/extractor 500 can be used in a directly anterior approach (Fig. 5v), and either of two anteriolateral approaches (Figs. 5w-x). That is, the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from a directly anterior approach, and the pins 506a-b can be inserted into the first 560 and second 562 holes of the second hole configuration (Fig. 5v). And, the symmetric repositioner/extractor's shaft 502 can be inserted into the wound from either of the two anteriolateral approaches, and the pins 506a-b can be inserted into the first 560 and third 564 holes (for one of the two anteriolateral approaches) (Fig. 5w) or the second 562 and fourth 566 holes (for the other of the two anteriolateral approaches) (Fig. 5x) of the second hole configuration.

[00171] Also, for example, with reference to Figs. 5y-dd, regarding the second hole configuration, each of the left offset repositioner/extractor 510 and the right offset repositioner/extractor 520 can be used in any of three respective anteriolateral approaches.

That is, the right offset repositioner/extractor's shaft 522 can be inserted into the wound from any of its three possible anteriolateral approaches, and the right offset repositioner/extractor's pins 526a-b can then be placed into the first 560 and second 562 holes (Fig. 5y) (for a first of the three anteriolateral approaches), the first 560 and third 564 holes (Fig. 5z) (for a second of the three anteriolateral approaches), or the second 562 and fourth 566 holes (Fig. 5aa) (for a third of the three anteriolateral approaches). And, the left offset repositioner/extractor's shaft 512 can be inserted into the wound from any of its three possible anteriolateral approaches, and the left offset repositioner/extractor's pins 516a-b can then be placed into the first 560 and second 562 holes (Fig. 5bb) (for a first of the three anteriolateral approaches), the first 560 and third 564 holes (Fig. 5cc) (for a second of the three anteriolateral approaches), or the second 562 and fourth 566 holes (Fig. 5dd) (for a third of the three anteriolateral approaches). It should be noted that the alternate left offset 530 and alternate right offset 540 repositioners/extractors can also fit into the holes of the second hole configuration in the same manner as described here with regard to the left offset 510 and right offset 520 repositioners/extractors.

[00172] It should be noted from the illustrations in Figs. 5p-dd that the anteriolateral approaches are at a variety of angles relative to the anterior-posterior plane, and further that the illustrated angles are merely exemplary. That is, the invention encompasses additional approach angles, in that such additional approach angles are possible by (as described above) adding or deleting holes, and/or changing the location of holes, and/or changing the spacing between holes (in conjunction with changing the spacing between pins), and/or changing the angle at which the offset repositioner/extractors' pins are placed relative to one another and to the shaft of such repositioner/extractors.

[00173] As discussed above, once the pins are established in the two adjacent holes, manipulating the shaft of the repositioner/extractor will reposition the static trial or artificial intervertebral disc in the intervertebral space and/or extract it from the intervertebral space. The use of more than one pin (versus one pin) enables the static trial or artificial intervertebral disc to be rotated in either direction about a longitudinal axis passing through the intervertebral space.

[00174] A preferred embodiment of a leveler of the present invention will now be described.

[00175] Referring now to Figs. 6a-e, a leveler of the present invention is shown in bottom (Fig. 6a), side (Fig. 6b), front (Fig. 6c), top partial perspective (Fig. 6d), and bottom partial perspective (Fig. 6e) views. More particularly, Fig. 6d shows a top perspective view of the

distal end of the leveler, and Fig. 6e shows a bottom perspective view of the distal end of the leveler.

[00176] The leveler is provided primarily for establishing a parallel orientation of the baseplates (relative to one another), and/or securing the purchase of the stabilizing spikes, of an artificial intervertebral disc having features suitable for being manipulated by the leveler. Exemplary suitable artificial intervertebral discs are described in the '160 and '528 applications with regard to Figs. 8a-z, 9a-u, 10a-u, 11a-k, and 12a-p thereof and by the accompanying descriptions therefor (e.g., embodiments identified as the first, second, third, fourth, and fifth preferred embodiments of the fourth embodiment family, etc.). Regarding the features suitable for being manipulated by the leveler, such features include suitably formed inwardly facing surfaces of the baseplates of the artificial intervertebral disc.

[00177] More particularly, the leveler 600 includes a shaft 602 having a forked distal end formed by two opposing tongs 604a-b that are symmetric to one another about a longitudinal axis of the shaft 602. Each of the tongs 604a-b has an extent that initially curves laterally outward away from the shaft 602 and from the other tong's extent, to define a central pocket 606 forward of the shaft 602 between the tongs' extents. Each tong's extent then resumes a distal direction to become parallel to the shaft 602 and to the other tong's extent.

[00178] Each tong's extent has an upper surface 608a-b and a lower surface 610a-b. The upper surface 608a-b is preferably shaped to conform against the inwardly facing surface of a first (e.g., upper) baseplate of an artificial intervertebral disc, and the lower surface 610a-b is preferably shaped to conform against the inwardly facing surface of a second (e.g., lower) baseplate of the artificial intervertebral disc, so that insertion of the forked distal end of the leveler 600 between the baseplates, with the central pocket 606 of the distal end avoiding the central portion of the artificial intervertebral disc, and with the upper 608a-b and lower surfaces 610a-b so engaging the inwardly facing surfaces of the baseplates, causes the baseplates to be placed in parallel orientation with respect to one another.

[00179] More particularly, for example for use with the exemplary artificial intervertebral disc of Figs. 1g-n, the upper surface 608a-b of each extent is flat, except for a tapered section 612a-b at the distal tip of the extent, which tapered section narrows the tip, and the lower surface 610a-b of each extent is curved to form opposing concave contours 614a-b that are cooperatively shaped to conform against the inwardly facing surface of the convex structure of the artificial intervertebral disc.

[00180] The preferred use of the leveler 600 is as follows. As discussed above, once the intervertebral space has been prepared and distracted to a dimension that will accept the artificial intervertebral disc to be implanted, the artificial intervertebral disc 160 is engaged at its lower baseplate 168b by the inserter/impactor 400,4000 discussed above. During insertion
5 (and, if necessary, impaction) of the artificial intervertebral disc 160 into the intervertebral space, the upper baseplate 168a remains free to angulate with respect to the lower baseplate 168b, so that the angulation of the baseplates conforms to the angulation of the intervertebral space as the artificial intervertebral disc is being inserted therein. Typically, the endplates of the prepared and distracted intervertebral space will be lordotically angled with respect to one
10 another, due to the use of the static trials 100,1000 as described above, which are formed to have a lordotic taper as discussed above. Thus, when the artificial intervertebral disc is inserted into the intervertebral space, its baseplates will be lordotically angled with respect to one another. Once the artificial intervertebral disc 160 is inserted, the inserter/impactor 400,4000 can be disengaged, and the repositioner/extractors 500,510,520,530,540 discussed above can
15 be applied to the artificial intervertebral disc, if necessary to achieve a more optimal positioning.

[00181] Once the positioning is established, the leveler 600 is preferably applied to the artificial intervertebral disc 160. The forked distal end of the leveler 600 is inserted so that the extents 604a-b are placed between the inwardly facing surface 164a of the upper baseplate 168a and the inwardly facing surface 164b of the convex structure 162 on the lower baseplate
20 168b, and so that the central pocket 606 of the leveler 600 avoids the ball-and-socket joint of the artificial intervertebral disc 160. If the baseplates are lordotically angled with respect to one another, the tapered sections 612a-b of the upper surfaces 608a-b of the forked distal end will be approximately parallel to, and will first encounter, the angled inwardly facing surface 164a of the upper baseplate 168a. At the same time, the concave contours 614a-b of the lower
25 surfaces 610a-b will accommodate the inwardly facing surface 164b of the convex structure 162 on the lower baseplate 168b. As the tapered sections 612a-b press against the inwardly facing surface 164a of the upper baseplate 168a, and the concave contours 614a-b slip into place against the inwardly facing surface 164b of the convex structure 162 on the lower baseplate 168b, the tapers 612a-b will function as wedges to force the posterior portion of the upper
30 baseplate 168a away from the posterior portion of the lower baseplate 168b. Accordingly, as the posterior portions are being separated, the stabilizing spikes 188a-b on the outwardly facing surfaces 186a-b of the baseplates 168a-b find or secure their purchase in the hard bone of the outer ring of the vertebral body endplates. When the forked distal end is fully seated (stops

616a-b are provided to butt up against the anterior portions of the baseplates 168a-b to prevent the forked distal end from being inserted too far), the extents of the tongs 604a-b hold the baseplates 168a-b parallel to one another, and so that the spikes 188a-b are fully engaged in the endplates. The surgeon then slips the leveler 600 out from between the baseplates 168a-b, and out from the wound and completes the procedure. A handle 618 is provided at a proximal end of the shaft 602 for pushing, pulling, and otherwise manipulating the leveler 600 as needed.

[00182] While there has been described and illustrated specific embodiments of instrumentation, it will be apparent to those skilled in the art that variations and modifications are possible without deviating from the broad spirit and principle of the invention. The invention, therefore, shall not be limited to the specific embodiments discussed herein.

CLAIMSWhat is claimed is:

- 5 1. A spinal orthopedic device and tool set, comprising
 an intervertebral spacer device having first and second baseplates mounted to one
 another such that the first and second baseplates are articulatable relative to one another,
 wherein at least one of the baseplates has an angled perimeter; and
 a manipulation tool having a correspondingly angled distal end, such that when the
10 correspondingly angled distal end of the manipulation tool is engaged with the angled perimeter
 of the at least one of the baseplates, movement of the at least one of the baseplates relative to
 the correspondingly angled distal end of the manipulation tool is limited by interference between
 the angled perimeter of the at least one of the baseplates and the correspondingly angled distal
15 end of the manipulation tool, such that the at least one of the baseplates is manipulatable using
 the manipulation tool.
2. The spinal orthopedic device and tool set of claim 1, wherein the angled
 perimeter of the at least one of the baseplates comprises a protruding corner of the at least one
 of the baseplates, and wherein the correspondingly angled distal end of the manipulation tool
20 comprises a recessed corner of the correspondingly angled distal end.
3. The spinal orthopedic device and tool set of claim 2, wherein the at least one of
 the baseplates has at least one engagement hole adjacent the protruding corner; and the
 correspondingly angled distal end of the manipulation tool supports an extendible and
25 retractable post that when extended is engageable with the engagement hole and when
 retracted while so engaged holds the angled perimeter of the at least one of the baseplates
 against the correspondingly angled distal end of the manipulation tool, such that the at least one
 of the baseplates is manipulatable using the manipulation tool.
- 30 4. The spinal orthopedic device and tool set of claim 3, wherein the at least one of
 the baseplates has at least a pair of engagement holes, each hole of the at least one pair being
 separated from the other hole of the at least one pair by a space having a length, and the spinal

orthopedic device and tool set further comprises a second manipulation tool, the second manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

5. The spinal orthopedic device and tool set of claim 2, wherein the angled perimeter of the at least one of the baseplates comprises at least two flat perimeter surfaces converging to form the protruding corner of the at least one of the baseplates, and wherein the correspondingly angled distal end of the manipulation tool comprises at least two flat surfaces converging to form the recessed corner of the correspondingly angled distal end.

6. The spinal orthopedic device and tool set of claim 5, wherein the at least one of the baseplates has at least one engagement hole adjacent at least one of the flat surfaces; and the correspondingly angled distal end of the manipulation tool supports an extendible and retractable post that when extended is engageable with the engagement hole and when retracted while so engaged holds the angled perimeter of the at least one of the baseplates against the correspondingly angled distal end of the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

7. The spinal orthopedic device and tool set of claim 6, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal orthopedic device and tool set further comprises a second manipulation tool, the second manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

8. The spinal orthopedic device and tool set of claim 1, wherein the angled perimeter of the at least one of the baseplates comprises three flat perimeter surfaces forming two protruding corners of the at least one of the baseplates, a first of the flat perimeter surfaces converging with a second of the flat perimeter surfaces to form a first of the protruding corners, the first of the flat perimeter surfaces also converging with a third of the flat perimeter surfaces to form a second of the protruding corners; and wherein

the correspondingly angled distal end of the manipulation tool comprises three flat surfaces forming two recessed corners of the correspondingly angled distal end of the manipulation tool, a first of the flat surfaces converging with a second of the flat surfaces to form a first of the recessed corners, the first of the flat surfaces also converging with a third of the flat surfaces to form a second of the recessed corners.

9. The spinal orthopedic device and tool set of claim 8, wherein the at least one of the baseplates has at least one engagement hole adjacent at least one of the flat surfaces; and the correspondingly angled distal end of the manipulation tool supports an extendible and retractable post that when extended is engageable with the engagement hole and when retracted while so engaged holds the angled perimeter of the at least one of the baseplates against the correspondingly angled distal end of the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

10. The spinal orthopedic device and tool set of claim 9, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal orthopedic device and tool set further comprises a second manipulation tool, the second manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

11. The spinal orthopedic device and tool set of claim 8, wherein the intervertebral spacer device is engageable for manipulation using the manipulation tool by positioning the first

protruding corner in the first recessed corner, and positioning the second protruding corner in the second recessed corner.

12. The spinal orthopedic device and tool set of claim 11, wherein the intervertebral
5 spacer device is also engageable for manipulation using the manipulation tool by positioning the first protruding corner in the second recessed corner.

13. The spinal orthopedic device and tool set of claim 12, wherein the intervertebral
10 spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corner in the first recessed corner.

14. The spinal orthopedic device and tool set of claim 11, wherein the intervertebral
15 spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corner in the first recessed corner.

15. The spinal orthopedic device and tool set of claim 8, wherein the first flat
perimeter surface of the at least one of the baseplates is longer than the first flat surface of the
angled distal end.

20 16. The spinal orthopedic device and tool set of claim 8, wherein each of the flat
perimeter surfaces faces a respective desired surgical approach aspect of the at least one of the
baseplates.

25 17. The spinal orthopedic device and tool set of claim 1516 wherein the first flat
perimeter surface faces an anterior aspect of the at least one of the baseplates.

18. The spinal orthopedic device and tool set of claim 17, wherein the second flat
perimeter surface faces a left antero-lateral aspect of the at least one of the baseplates, and the
third flat perimeter surface faces a right antero-lateral aspect of the at least one of the
30 baseplates.

19. The spinal orthopedic device and tool set of claim 1, wherein each of the baseplates has an angled perimeter, and the angled perimeters are simultaneously engageable with the correspondingly angled distal end of the manipulation tool.

5 20. The spinal orthopedic device and tool set of claim 19, wherein the angled perimeters of the baseplates are similarly configured.

21. The spinal orthopedic device and tool set of claim 20, wherein the angled perimeter of the first baseplate comprises three flat perimeter surfaces forming two protruding
10 corners of the first baseplate, a first of the flat perimeter surfaces converging with a second of the flat perimeter surfaces to form a first of the protruding corners, the first of the flat perimeter surfaces also converging with a third of the flat perimeter surfaces to form a second of the protruding corners; and wherein

15 the angled perimeter of the second baseplate comprises three flat perimeter surfaces forming two protruding corners of the second baseplate, a first of the flat perimeter surfaces converging with a second of the flat perimeter surfaces to form a first of the protruding corners, the first of the flat perimeter surfaces also converging with a third of the flat perimeter surfaces to form a second of the protruding corners; and wherein

20 the correspondingly angled distal end of the manipulation tool comprises three flat surfaces forming two recessed corners of the correspondingly angled distal end of the manipulation tool, a first of the flat surfaces converging with a second of the flat surfaces to form a first of the recessed corners, the first of the flat surfaces also converging with a third of the flat surfaces to form a second of the recessed corners.

25 22. The spinal orthopedic device and tool set of claim 21, wherein the intervertebral spacer device is engageable for manipulation using the manipulation tool by positioning the first protruding corners in the first recessed corner, and positioning the second protruding corners in the second recessed corner.

30 23. The spinal orthopedic device and tool set of claim 22, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the first protruding corners in the second recessed corner.

24. The spinal orthopedic device and tool set of claim 23, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corners in the first recessed corner.

5 25. The spinal orthopedic device and tool set of claim 22, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corners in the first recessed corner.

10 26. The spinal orthopedic device and tool set of claim 21, wherein each of the first flat perimeter surfaces of the baseplates is longer than the first flat surface of the angled distal end.

27. The spinal orthopedic device and tool set of claim 21, wherein the first flat perimeter surfaces face an anterior aspect of the intervertebral spacer device.

15 28. The spinal orthopedic device and tool set of claim 27, wherein the second flat perimeter surfaces face a left antero-lateral aspect of the intervertebral spacer device, and the third flat perimeter surfaces face a right antero-lateral aspect of the intervertebral spacer device.

20 29. The spinal orthopedic device and tool set of claim 21, wherein the three flat surfaces of the correspondingly angled distal end of the manipulation tool are an upper set of three flat surfaces, and the two recessed corners of the correspondingly angled distal end of the manipulation tool are two upper recessed corners; and wherein the correspondingly angled distal end of the manipulation tool comprises six flat surfaces, the six flat surfaces comprising the upper set of three flat surfaces forming the two upper recessed corners of the angled distal end of the manipulation tool; and wherein

25 the six flat surfaces further comprise a lower set of three flat surfaces forming two lower recessed corners of the angle distal end of the manipulation tool, a first of the three lower flat surfaces converging with a second of the three lower flat surfaces to form a first of the two lower recessed corners, the first of the three lower flat surfaces also converging with a third of the
30 three lower flat surfaces to form a second of the two lower recessed corners.

30. The spinal orthopedic device and tool set of claim 29, wherein the intervertebral spacer device is engageable for manipulation using the manipulation tool by positioning the first

protruding corner of the first baseplate in the first upper recessed corner, and positioning the second protruding corner of the first baseplate in the second upper recessed corner, and positioning the first protruding corner of the second baseplate in the first lower recessed corner, and positioning the second protruding corner of the second baseplate in the second lower recessed corner.

31. The spinal orthopedic device and tool set of claim 30, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the first protruding corner of the first baseplate in the second upper recessed corner, and positioning the first protruding corner of the second baseplate in the second lower recessed corner.

32. The spinal orthopedic device and tool set of claim 31, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corner of the first baseplate in the first upper recessed corner, and positioning the second protruding corner of the second baseplate in the first lower recessed corner.

33. The spinal orthopedic device and tool set of claim 30, wherein the intervertebral spacer device is also engageable for manipulation using the manipulation tool by positioning the second protruding corner of the first baseplate in the first upper recessed corner, and positioning the second protruding corner of the second baseplate in the first lower recessed corner.

34. The spinal orthopedic device and tool set of claim 29, wherein the first flat perimeter surface of the first baseplate is longer than the first upper flat surface of the angled distal end, and the first flat perimeter surface of the second baseplate is longer than the first lower flat surface of the angled distal end.

35. The spinal orthopedic device and tool set of claim 29, wherein the first flat perimeter surfaces face an anterior aspect of the intervertebral spacer device.

36. The spinal orthopedic device and tool set of claim 35, wherein the second flat perimeter surfaces face a left antero-lateral aspect of the intervertebral spacer device, and the third flat perimeter surfaces face a right antero-lateral aspect of the intervertebral spacer device.

37. The spinal orthopedic device and tool set of claim 1, wherein the angled distal end of the manipulation tool is engageable with the angled perimeter of the at least one of the baseplates in a plurality of ways, each of the plurality of ways establishes a respective desired surgical approach angle for manipulating the intervertebral spacer device.

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38. The spinal orthopedic device and tool set of claim 37, wherein one of the plurality of ways establishes an anterior surgical approach angle.

39. The spinal orthopedic device and tool set of claim 38, wherein the one of the plurality of ways is a first of the plurality of ways, and wherein a second of the plurality of ways establishes a left antero-lateral surgical approach angle, and wherein a third of the plurality of ways establishes a right antero-lateral surgical approach angle.

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40. The spinal orthopedic device and tool set of claim 1, wherein the angled perimeter of the at least one of the baseplates includes a plurality of flat surfaces adjacent one another and the correspondingly angled distal end has a central flat surface flanked by at least one flat surface; and wherein the at least one of the baseplates is engageable for manipulation using the manipulation tool by positioning the primary flat surface against any one of the plurality of flat surfaces, such that the at least one flanking flat surface is against another of the plurality of flat surfaces.

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41. The spinal orthopedic device and tool set of claim 1, wherein the angled perimeter of the at least one of the baseplates includes a plurality of flat surfaces adjacent one another and the correspondingly angled distal end has a central flat surface flanked by two flat surfaces; and wherein the at least one of the baseplates is engageable for manipulation using the manipulation tool by positioning the primary flat surface against any one of the plurality of flat surfaces, such that at least one of the two flanking flat surfaces is against another of the plurality of flat surfaces.

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42. The spinal orthopedic device and tool set of claim 41, wherein the at least one of the baseplates has at least one engagement hole adjacent at least one of the flat surfaces of the angled perimeter; and the correspondingly angled distal end of the manipulation tool supports an extendible and retractable post that when extended is engageable with the engagement hole

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and when retracted while so engaged holds the angled perimeter of the at least one of the baseplates against the correspondingly angled distal end of the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

5 43. The spinal orthopedic device and tool set of claim 42, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal orthopedic device and tool set further comprises a second manipulation tool, the second
10 manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

15 44. The spinal orthopedic device and tool set of claim 41, wherein the plurality of flat surfaces includes a flat surface facing an anterior aspect of the at least one baseplate.

20 45. The spinal orthopedic device and tool set of claim 44, wherein the plurality of flat surfaces further includes a flat surface facing a left antero-lateral aspect of the at least one baseplate, and a flat surface facing a right antero-lateral aspect of the at least one baseplate.

25 46. The spinal orthopedic device and tool set of claim 1, wherein the angled perimeter of the at least one of the baseplates includes a plurality of surfaces adjacent one another, at least every other ones of the plurality of surfaces being flat, and the correspondingly angled distal end has a central surface flanked by two flat surfaces; and wherein the at least one of the baseplates is engageable for manipulation using the manipulation tool by positioning the two flanking flat surfaces against any two of the flat surfaces of the at least one of the
30 baseplates,.

 47. The spinal orthopedic device and tool set of claim 41, wherein the at least one of the baseplates has at least one engagement hole adjacent at least one of the surfaces of the angled perimeter; and the correspondingly angled distal end of the manipulation tool supports an

extendible and retractable post that when extended is engageable with the engagement hole and when retracted while so engaged holds the angled perimeter of the at least one of the baseplates against the correspondingly angled distal end of the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

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48. The spinal orthopedic device and tool set of claim 47, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal orthopedic device and tool set further comprises a second manipulation tool, the second
10 manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes,
15 such that the at least one of the baseplates is manipulatable using the manipulation tool.

49. The spinal orthopedic device and tool set of claim 46, wherein a pair of flat surfaces of the plurality of surfaces flank an anterior aspect of the at least one baseplate.

20 50. The spinal orthopedic device and tool set of claim 49, wherein the pair of flat surfaces of the plurality of surfaces is a first pair, and a second pair of flat surfaces of the plurality of surfaces further flank a left antero-lateral aspect of the at least one baseplate, and a third pair of flat surfaces of the plurality of surfaces flank a right antero-lateral aspect of the at least one baseplate.

25

51. The spinal orthopedic device and tool set of claim 1, wherein the at least one of the baseplates has at least one engagement hole on a perimetrical region of the at least one of the baseplates; and the correspondingly angled distal end of the manipulation tool supports an extendible and retractable post that when extended is engageable with the engagement hole
30 and when retracted while so engaged holds the angled perimeter of the at least one of the baseplates against the correspondingly angled distal end of the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

52. The spinal orthopedic device and tool set of claim 51, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal orthopedic device and tool set further comprises a second manipulation tool, the second
5 manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes,
10 such that the at least one of the baseplates is manipulatable using the manipulation tool.

53. The spinal orthopedic device and tool set of claim 51, wherein the at least one of the baseplates has a plurality of engagement holes and the post is engageable with any of the plurality of engagement holes.
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54. The spinal orthopedic device and tool set of claim 53, wherein each of the plurality of engagement holes is at a respective desired surgical approach aspect of the at least one of the baseplates.

20 55. The spinal orthopedic device and tool set of claim 54, wherein each baseplate has an inwardly facing surface and an outwardly facing surface; and wherein the baseplates are mounted to one another such that the inwardly facing surfaces face one another and the outwardly facing surfaces face away from one another; and wherein one of the inwardly facing surfaces has the plurality of engagement holes.

25 56. The spinal orthopedic device and tool set of claim 54, wherein one of the desired surgical approach aspects is an anterior aspect of the at least one of the baseplates.

30 57. The spinal orthopedic device and tool set of claim 54, wherein at least one of the desired surgical approach aspects is an antero-lateral aspect of the at least one of the baseplates.

58. The spinal orthopedic device and tool set of claim 51, wherein the at least one of the baseplates has three engagement holes and the post is engageable with any of the three of engagement holes.

5 59. The spinal orthopedic device and tool set of claim 58, wherein each of the three engagement holes is at a respective desired surgical approach aspect of the at least one of the baseplates.

10 60. The spinal orthopedic device and tool set of claim 59, wherein one of the desired surgical approach aspects is an anterior aspect of the at least one of the baseplates.

15 61. The spinal orthopedic device and tool set of claim 60, wherein each baseplate has an inwardly facing surface and an outwardly facing surface; and wherein the baseplates are mounted to one another such that the inwardly facing surfaces face one another and the outwardly facing surfaces face away from one another; and wherein one of the inwardly facing surfaces has the plurality of engagement holes.

20 62. The spinal orthopedic device and tool set of claim 60, wherein the other desired surgical approach aspects are a left antero-lateral aspect and a right antero-lateral aspect of the at least one of the baseplates.

25 63. The spinal orthopedic device and tool set of claim 51, wherein the at least one engagement hole has a longitudinal axis parallel to both an anterior-posterior plane and a medial-lateral plane of the intervertebral spacer device.

30 64. A spinal orthopedic device and tool set, comprising
an intervertebral spacer device having first and second baseplates mounted to one another such that the first and second baseplates are articulatable relative to one another, wherein at least one of the baseplates has at least one engagement hole on a perimetrical region of the at least one of the baseplates; and

a manipulation tool having a distal end supporting an extendible and retractable post that when extended is engageable with the engagement hole and when retracted while so engaged

holds the baseplate against the manipulation tool, such that the at least one of the baseplates is manipulatable using the manipulation tool.

5 65. The spinal orthopedic device and tool set of claim 64, wherein the at least one of the baseplates has a plurality of engagement holes and the post is engageable with any of the plurality of engagement holes.

10 66. The spinal orthopedic device and tool set of claim 65, wherein the at least one of the baseplates has at least a pair of engagement holes, each hole of the at least one pair being separated from the other hole of the at least one pair by a space having a length, and the spinal
15 orthopedic device and tool set further comprises a second manipulation tool, the second manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that
20 movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

25 67. The spinal orthopedic device and tool set of claim 65, wherein each of the plurality of engagement holes is at a respective desired surgical approach aspect of the at least one of the baseplates.

30 68. The spinal orthopedic device and tool set of claim 67, wherein each baseplate has an inwardly facing surface and an outwardly facing surface; and wherein the baseplates are mounted to one another such that the inwardly facing surfaces face one another and the outwardly facing surfaces face away from one another; and wherein one of the inwardly facing surfaces has the plurality of engagement holes.

35 69. The spinal orthopedic device and tool set of claim 67, wherein one of the desired surgical approach aspects is an anterior aspect of the at least one of the baseplates.

70. The spinal orthopedic device and tool set of claim 67, wherein at least one of the desired surgical approach aspects is an antero-lateral aspect of the at least one of the baseplates.

5 71. The spinal orthopedic device and tool set of claim 64, wherein the at least one of the baseplates has three engagement holes and the post is engageable with any of the three of engagement holes.

10 72. The spinal orthopedic device and tool set of claim 71, wherein each of the three engagement holes is at a respective desired surgical approach aspect of the at least one of the baseplates.

15 73. The spinal orthopedic device and tool set of claim 72, wherein one of the desired surgical approach aspects is an anterior aspect of the at least one of the baseplates.

20 74. The spinal orthopedic device and tool set of claim 73, wherein each baseplate has an inwardly facing surface and an outwardly facing surface; and wherein the baseplates are mounted to one another such that the inwardly facing surfaces face one another and the outwardly facing surfaces face away from one another; and wherein one of the inwardly facing surfaces has the plurality of engagement holes.

25 75. The spinal orthopedic device and tool set of claim 73, wherein the other desired surgical approach aspects are a left antero-lateral aspect and a right antero-lateral aspect of the at least one of the baseplates.

76. The spinal orthopedic device and tool set of claim 64, wherein the at least one engagement hole has a longitudinal axis parallel to both an anterior-posterior plane and a medial-lateral plane of the intervertebral spacer device.

30 77. A spinal orthopedic device and tool set, comprising
an intervertebral spacer device having first and second baseplates mounted to one another such that the first and second baseplates are articulatable relative to one another, wherein at least one of the baseplates has at least one pair of engagement holes, each hole of

the at least one pair being separated from the other hole of the at least one pair by a space having a length; and

a manipulation tool having a distal end supporting a pair of engagement posts, each post of the pair being separated from the other post of the pair by a space having the length, such that the pair of engagement posts is positionable in the at least one pair of engagement holes such that movement of the at least one of the baseplates relative to the distal end of the manipulation tool is limited by interference between the engagement posts and the engaged engagement holes, such that the at least one of the baseplates is manipulatable using the manipulation tool.

78. The spinal orthopedic device and tool set of claim 77, wherein the at least one of the baseplates has at least two pairs of engagement holes; and wherein the pair of engagement posts is positionable in any pair of the at least two pairs of engagement holes.

79. The spinal orthopedic device and tool set of claim 78, wherein the at least two pairs of engagement holes comprise three engagement holes, a first of the three engagement holes being separated from a second of the three engagement holes by a space having the length, the second of the three engagement holes being separated from a third of the three engagement holes by a space having the length.

80. The spinal orthopedic device and tool set of claim 78, wherein the at least one of the baseplates has at least three pairs of engagement holes; and the pair of engagement posts is positionable in any pair of the at least three pairs of engagement holes.

81. The spinal orthopedic device and tool set of claim 80, wherein the at least three pairs of engagement holes comprise four engagement holes, a first of the four engagement holes being separated from a second of the four engagement holes by a space having the length, the second of the four engagement holes being separated from a third of the four engagement holes by a space having the length, the third of the four engagement holes being separated from a fourth of the four engagement holes by a space having the length.

82. The spinal orthopedic device and tool set of claim 77, wherein each of the at least one pair of engagement holes has a longitudinal axis parallel to both an anterior-posterior plane and a medial-lateral plane of the intervertebral spacer device.

5 83. The spinal orthopedic device and tool set of claim 77, wherein each baseplate has an inwardly facing surface and an outwardly facing surface; and wherein the baseplates are mounted to one another such that the inwardly facing surfaces face one another and the outwardly facing surfaces face away from one another; and wherein one of the inwardly facing surfaces has at least one pair of the at least one pair of engagement holes.

10 84. The spinal orthopedic device and tool set of claim 83, wherein the inwardly facing surface of the first baseplate has the at least one pair of the at least one pair of engagement holes, and wherein the inwardly facing surface of the second baseplate has at least one other pair of the at least one pair of engagement holes.

15 85. The spinal orthopedic device and tool set of claim 77, wherein the inwardly facing surface of the first baseplate has three pairs of engagement holes, and the inwardly facing surface of the second baseplate has two pairs of engagement holes; and wherein the pair of engagement posts is positionable in any of the pairs of engagement holes.

20 86. The spinal orthopedic device and tool set of claim 85, wherein the three pairs of engagement holes comprise four engagement holes, a first of the four engagement holes being separated from a second of the four engagement holes by a space having the length, the first of the four engagement holes being separated from a third of the four engagement holes by a space having the length, the second of the four engagement holes being separated from a fourth of the four engagement holes by a space having the length.

25 87. The spinal orthopedic device and tool set of claim 86, wherein the two pairs of engagement holes comprise three engagement holes, a first of the three engagement holes being separated from a second of the three engagement holes by a space having the length, the first of the three engagement holes being separated from a third of the three engagement holes by a space having the length.

88. The spinal orthopedic device and tool set of claim 87, wherein the first and second engagement holes of the four engagement holes are evenly distributed about an anterior aspect of the inwardly facing surface of the first baseplate, the first and third engagement holes of the four engagement holes are evenly distributed about a left antero-lateral aspect of the inwardly facing surface of the first baseplate, and the second and fourth engagement holes of the four engagement holes are evenly distributed about a right antero-lateral aspect of the inwardly facing surface of the first baseplate; and wherein the first engagement hole of the three engagement holes is centered at an anterior aspect of the inwardly facing surface of the second baseplate, the second engagement hole of the three engagement holes is centered at a left antero-lateral aspect of the inwardly facing surface of the second baseplate, and the third engagement hole of the three engagement holes is centered at a right antero-lateral aspect of the inwardly facing surface of the second baseplate.

89. The spinal orthopedic device and tool set of claim 88, wherein the anterior aspect of the inwardly facing surface of the first baseplate and the anterior aspect of the inwardly facing surface of the second baseplates are co-planar; and wherein the left antero-lateral aspect of the inwardly facing surface of the first baseplate and the left antero-lateral aspect of the inwardly facing surface of the second baseplates are co-planar; and wherein the right antero-lateral aspect of the inwardly facing surface of the first baseplate and the right antero-lateral aspect of the inwardly facing surface of the second baseplates are co-planar.

90. The spinal orthopedic device and tool set of claim 77, wherein the at least one pair of engagement holes comprises at least one engagement hole centered at a first desired surgical approach aspect of the at least one of the baseplates, and at least one engagement hole centered at a second desired surgical approach aspect of the at least one of the baseplates.

91. The spinal orthopedic device and tool set of claim 90, wherein the first desired surgical approach aspect is an anterior aspect of the at least one of the baseplates, and the second desired surgical approach aspect is an antero-lateral aspect of the at least one of the baseplates.

92. The spinal orthopedic device and tool set of claim 90, wherein the at least one pair of engagement holes comprises two pairs of engagement holes, and the two pairs of engagement holes comprise three engagement holes, a first of the three engagement holes being separated from a second of the three engagement holes by a space having the length, the second of the three engagement holes being separated from a third of the three engagement holes by a space having the length; and wherein the second engagement hole of the three engagement holes is centered at the second desired surgical approach aspect of the at least one of the baseplates, and wherein the first engagement hole of the three engagement holes is positioned at the first desired surgical approach aspect of the at least one of the baseplates, and wherein the third engagement hole of the three engagement holes is positioned at a third desired surgical approach aspect of the at least one of the baseplates.

93. The spinal orthopedic device and tool set of claim 92, wherein the first desired surgical approach aspect is an anterior aspect of the at least one of the baseplates, the second desired surgical approach aspect is left antero-lateral aspect of the at least one of the baseplates, and the third desired surgical approach aspect is a right antero-lateral aspect of the at least one of the baseplates.

94. The spinal orthopedic device and tool set of claim 77, wherein the at least one pair of engagement holes comprises first and second engagement holes evenly distributed about a desired surgical approach aspect of the at least one of the baseplates.

95. The spinal orthopedic device and tool set of claim 94, wherein the desired surgical approach aspect is an anterior aspect of the at least one of the baseplates.

96. The spinal orthopedic device and tool set of claim 95, wherein the desired surgical approach aspect is a first desired surgical approach aspect; and wherein the at least one pair of engagement holes comprises at least three pairs of engagement holes, and the at least three pairs of engagement holes comprise four engagement holes, the four engagement holes comprising the first and second engagement holes distributed about the first desired surgical approach aspect of the at least one of the baseplates, the four engagement holes further comprising a third engagement hole positioned such that the first engagement hole and the third engagement hole are evenly distributed about a second desired surgical approach

aspect of the at least one of the baseplates, the four engagement holes further comprising a fourth engagement hole positioned such that the second engagement hole and the fourth engagement hole are evenly distributed about a third desired surgical approach aspect of the at least one of the baseplates.

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97. The spinal orthopedic device and tool set of claim 96, wherein the first desired surgical approach aspect is an anterior aspect of the at least one of the baseplates, the second desired surgical approach aspect is left antero-lateral aspect of the at least one of the baseplates, and the third desired surgical approach aspect is a right antero-lateral aspect of the at least one of the baseplates.

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98. The spinal orthopedic device and tool set of claim 96, wherein the first of the four engagement holes is separated from the second of the four engagement holes by a space having the length, the first of the four engagement holes is separated from the third of the four engagement holes by a space having the length, and the second of the four engagement holes is separated from the fourth of the four engagement holes by a space having the length.

15

99. A spinal orthopedic device and tool set, comprising an intervertebral spacer device having first and second baseplates mounted to one another such that the first and second baseplates are articulatable relative to one another, wherein the perimetrical regions of the baseplates are separated by a spacing having a width, and wherein the perimetrical regions have at least one pair of opposing recesses having walls that define an access volume between the baseplates in which the perimetrical regions of the baseplates are separated by a spacing having a greater width; and

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a manipulation tool having a distal shaft having a relevant dimension greater than the width, but less than the greater width, such that the distal shaft is accommodated between the perimetrical regions of the baseplates only in the access volume, such that when the distal shaft of the manipulation tool is so accommodated, movement of the intervertebral spacer device relative to the distal shaft of the manipulation tool is limited by interference between the distal shaft and the walls of the recesses, such that the intervertebral spacer device is manipulatable using the manipulation tool.

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100. The spinal orthopedic device and tool set of claim 99, wherein the perimetrical regions have a plurality of opposing recess pairs.

101. The spinal orthopedic device and tool set of claim 99, wherein each access
5 volume is aligned with a desired surgical approach direction.

102. The spinal orthopedic device and tool set of claim 101, wherein at least one of the surgical approach directions is an anterior approach direction.

103. The spinal orthopedic device and tool set of claim 101, wherein the perimetrical
10 regions have three opposing recess pairs, each defining first, second, and third access volumes, respectively, each being aligned with an anterior approach direction, a left antero-lateral approach direction, and a right antero-lateral approach direction, respectively.

104. A spinal orthopedic device and tool set, comprising
15 an intervertebral spacer device having first and second baseplates mounted to one another such that the first and second baseplates are articulatable relative to one another, wherein the perimetrical regions of the baseplates are separated by a spacing having a width, and wherein at least one of the perimetrical regions has a recess opposite the other perimetrical
20 region, the recess having walls that define an access volume between the baseplates in which the perimetrical regions of the baseplates are separated by a spacing having a greater width; and

a manipulation tool having a distal shaft having a relevant dimension greater than the width, but less than the greater width, such that the distal shaft is accommodated between the
25 perimetrical regions of the baseplates only in the access volume, such that when the distal shaft of the manipulation tool is so accommodated, movement of the intervertebral spacer device relative to the distal shaft of the manipulation tool is limited by interference between the distal shaft and the walls of the recesses, such that the intervertebral spacer device is manipulatable using the manipulation tool.

105. The spinal orthopedic device and tool set of claim 104, wherein the at least one of
30 the perimetrical regions has a plurality of recesses, each defining a respective access volume.

106. The spinal orthopedic device and tool set of claim 104, wherein each access volume is aligned with a desired surgical approach direction.

5 107. The spinal orthopedic device and tool set of claim 106, wherein at least one of the surgical approach directions is an anterior approach direction.

10 108. The spinal orthopedic device and tool set of claim 107, wherein the at least one of the perimetrical regions has three recesses, each defining first, second, and third access volumes, respectively, each being aligned with an anterior approach direction, a left antero-lateral approach direction, and a right antero-lateral approach direction, respectively.

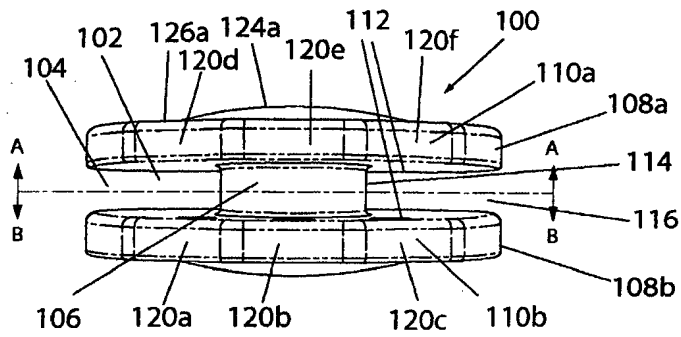


FIG. 1a

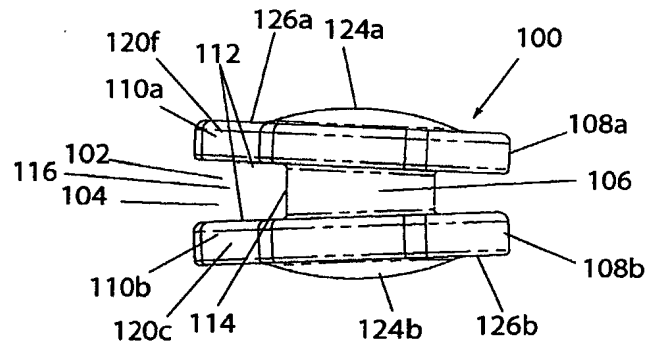


FIG. 1b

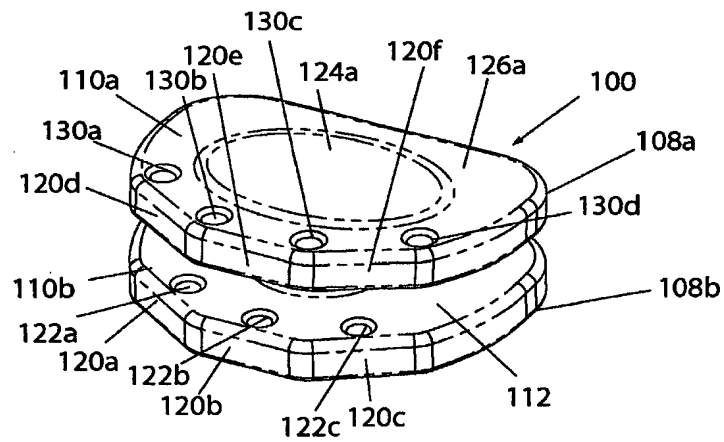


FIG. 1c

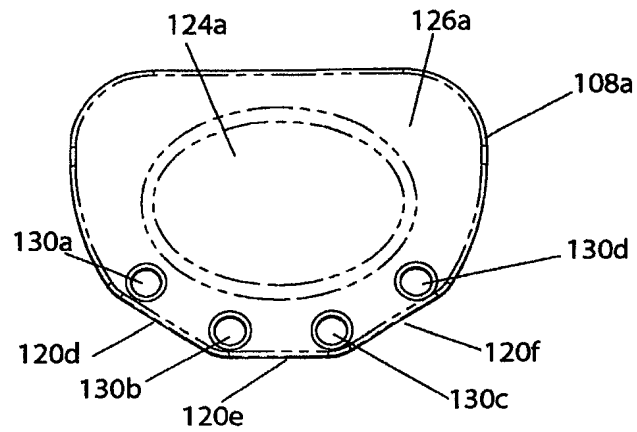


FIG. 1d

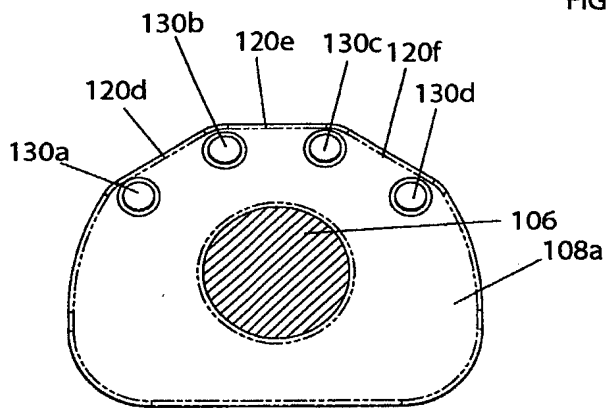


FIG. 1e
(Section A-A of Fig. 1a)

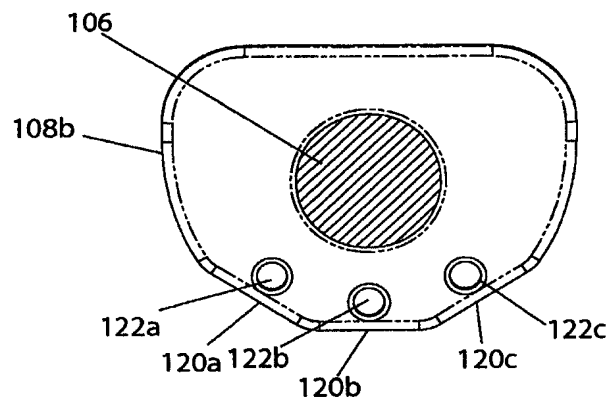


FIG. 1f
(Section B-B of Fig. 1a)

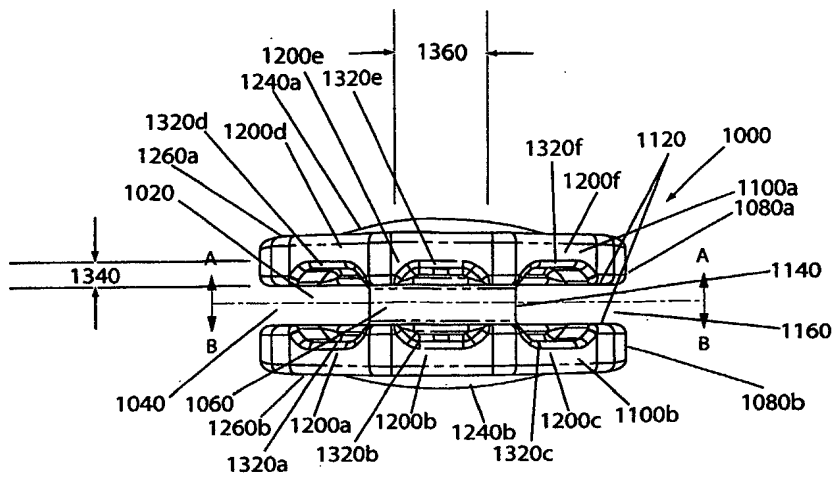


FIG. 1aa

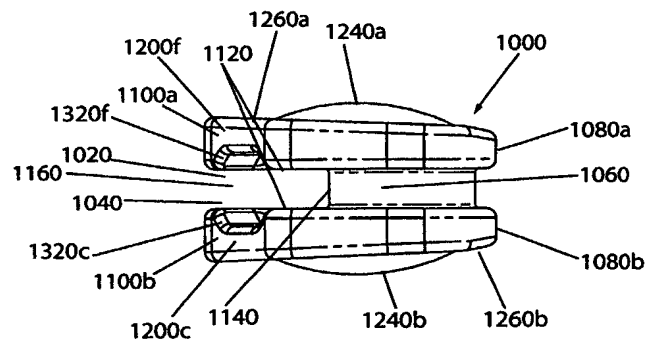


FIG. 1bb

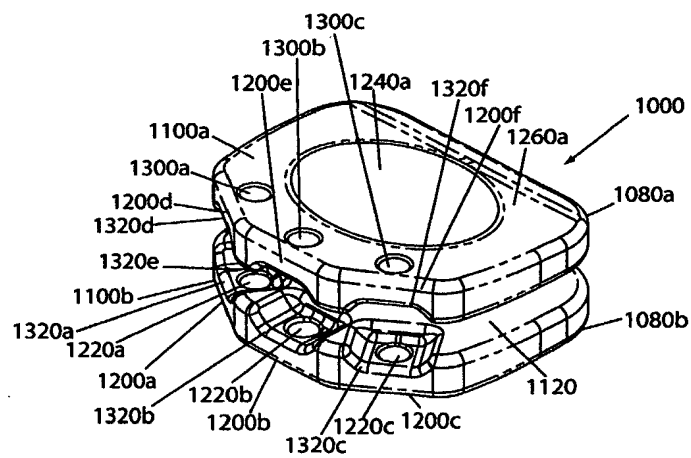


FIG. 1cc

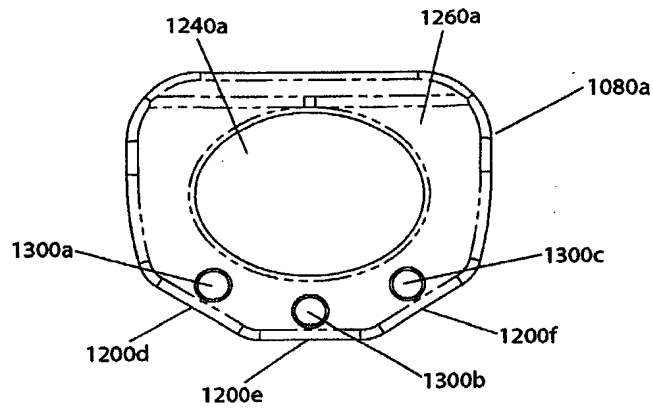


FIG. 1dd

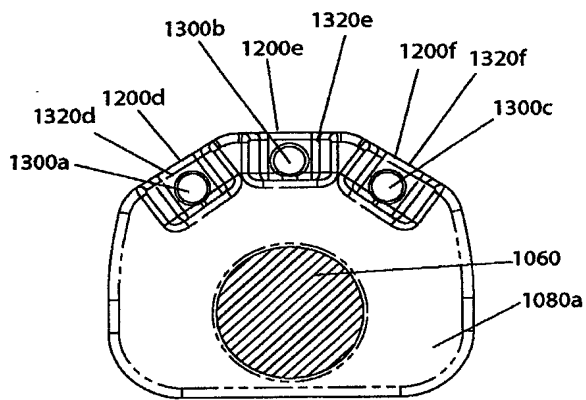


FIG. 1ee
(Section A-A of Fig. 1aa)

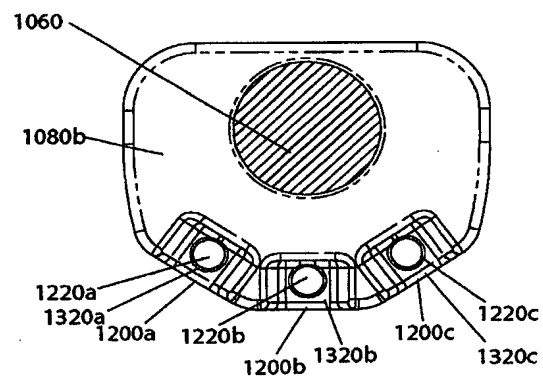


FIG. 1ff
(Section B-B of Fig. 1aa)

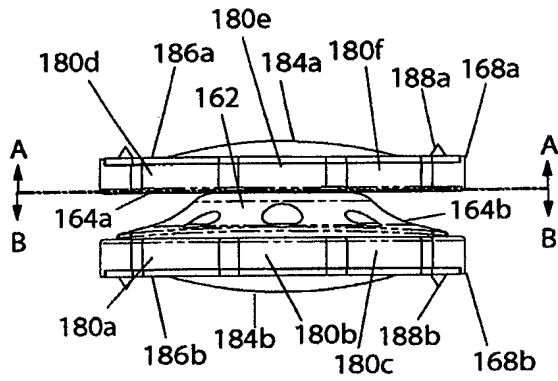


FIG. 1g

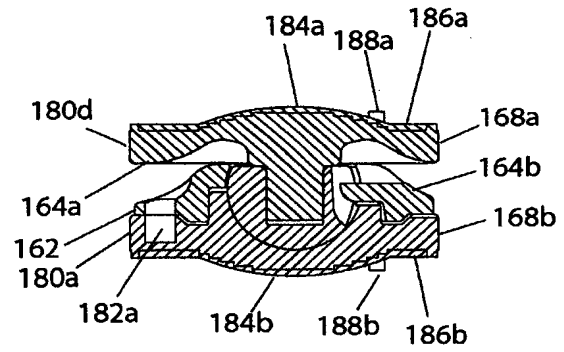


FIG. 1h
(Section C-C on Fig. 1i)

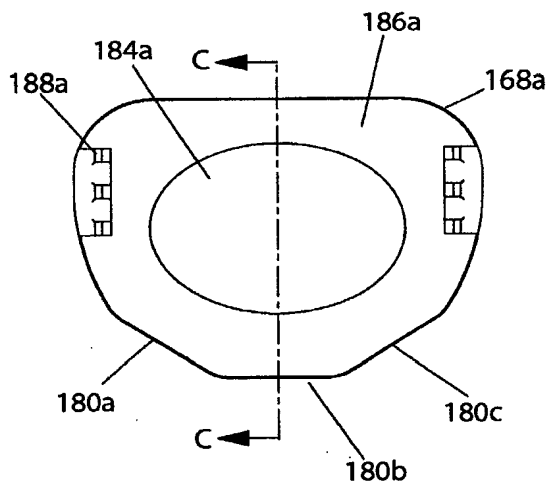


FIG. 1i

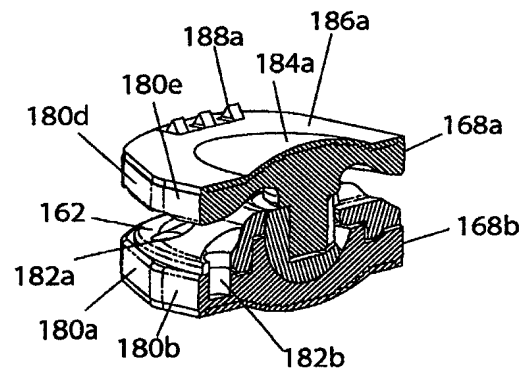


FIG. 1j
(Perspective of Fig. 1h)

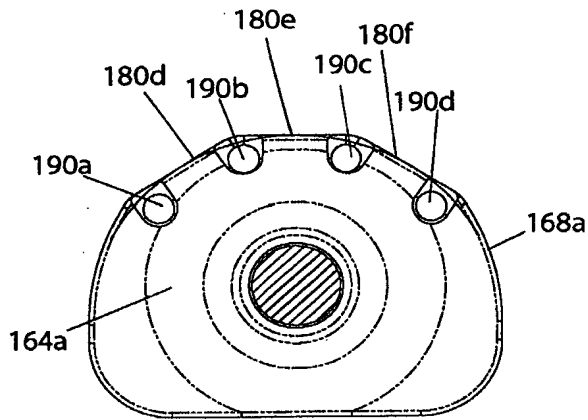


FIG. 1k
(Section A-A on Fig. 1g)

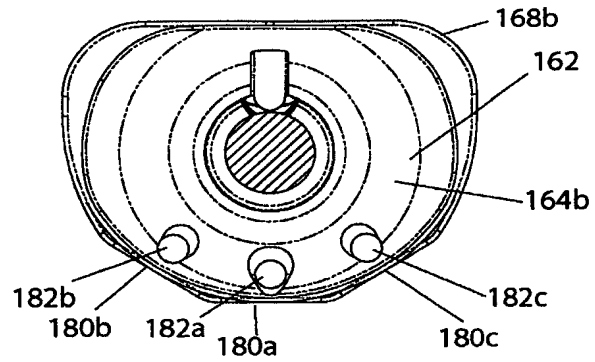


FIG. 1l
(Section B-B on Fig. 1g)

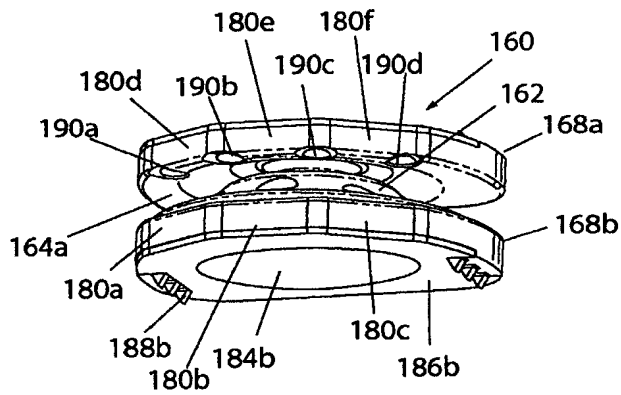


FIG. 1m

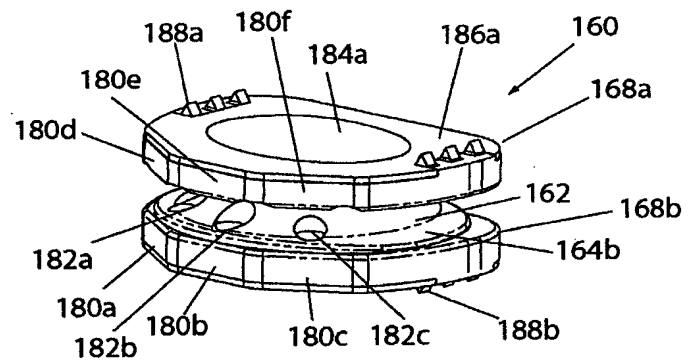
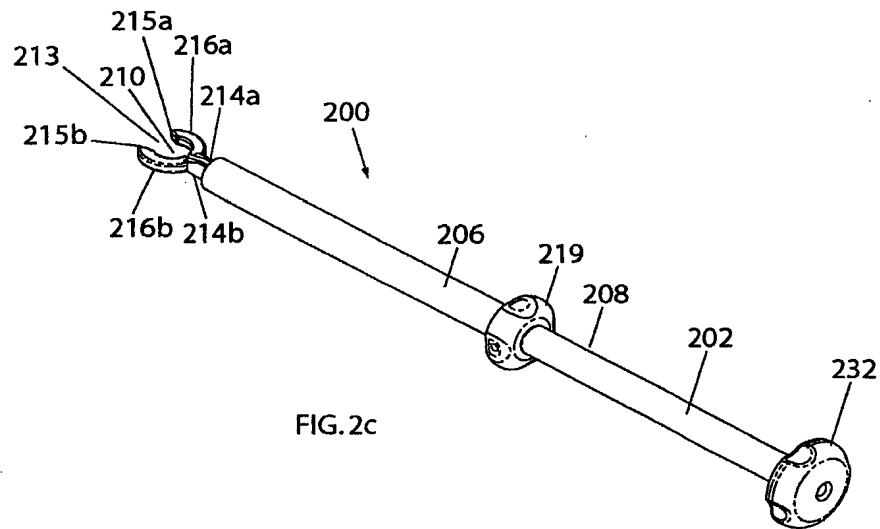
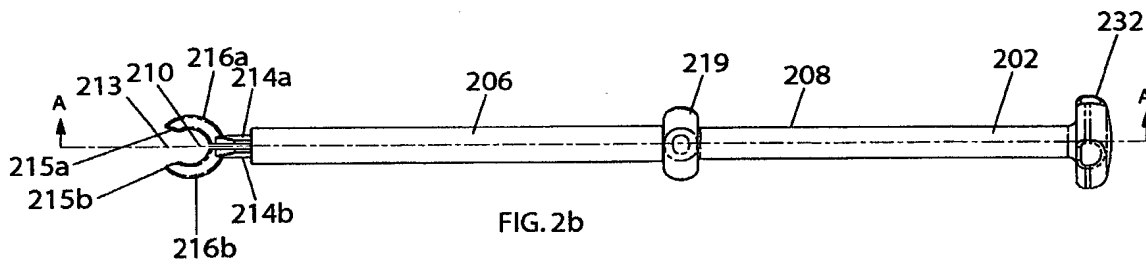
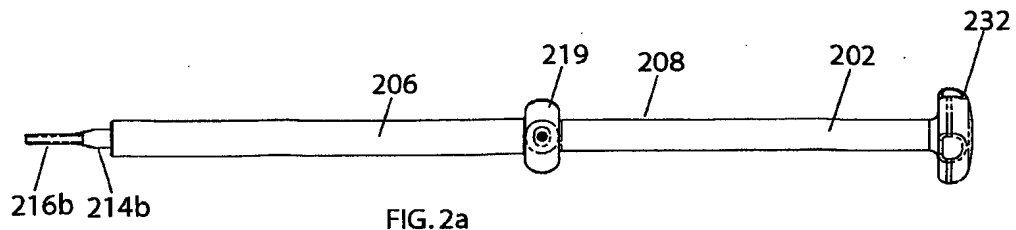
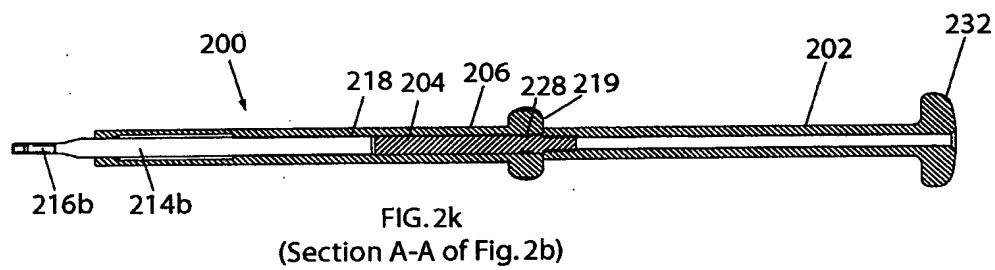
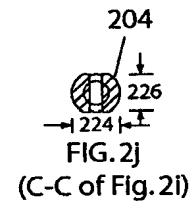
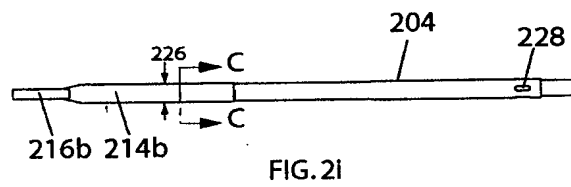
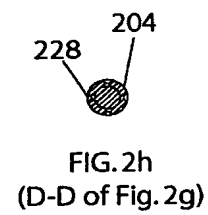
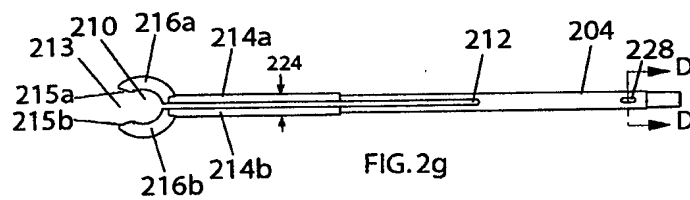
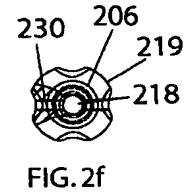
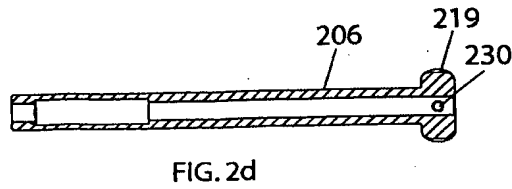
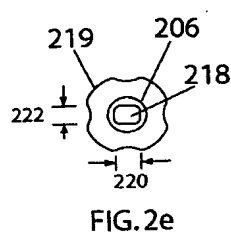


FIG. 1n





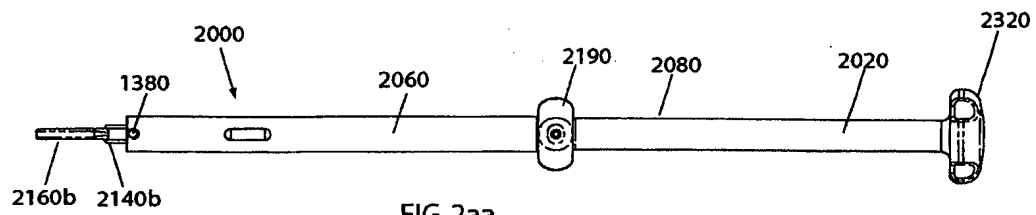


FIG. 2aa

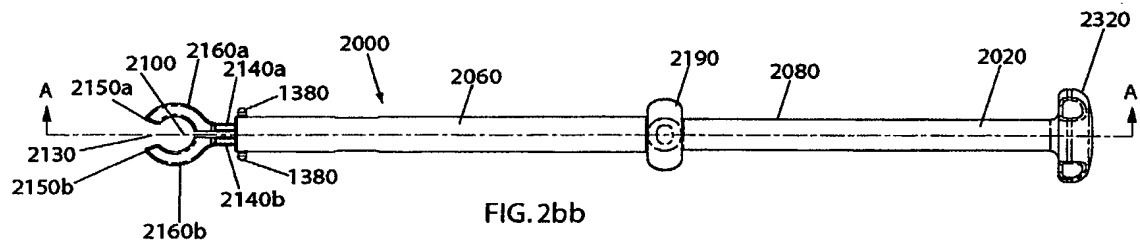


FIG. 2bb

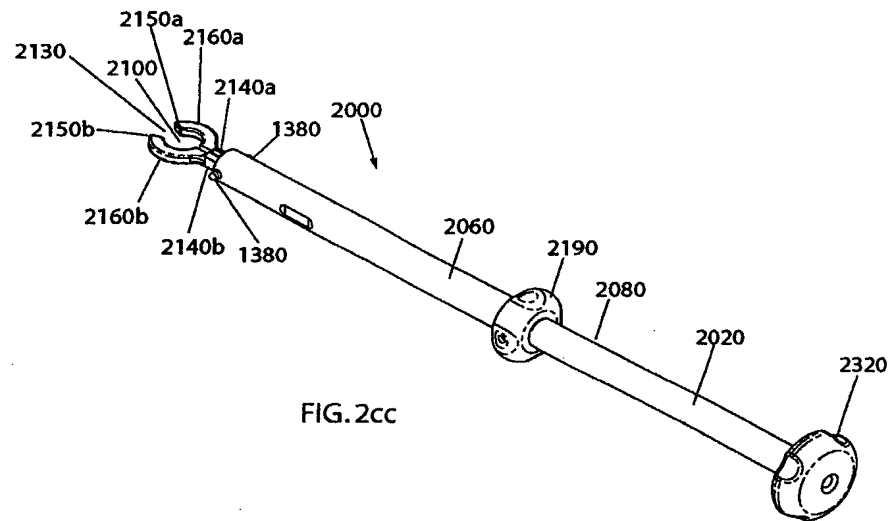
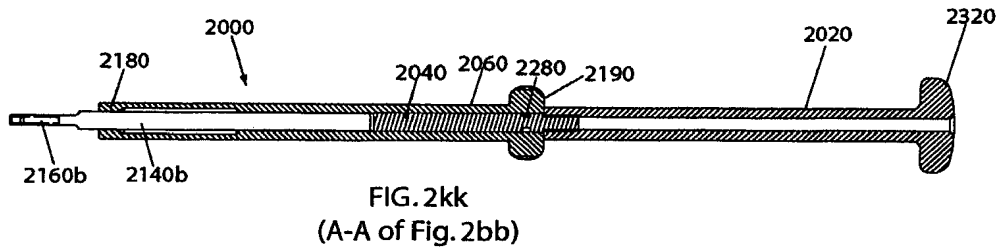
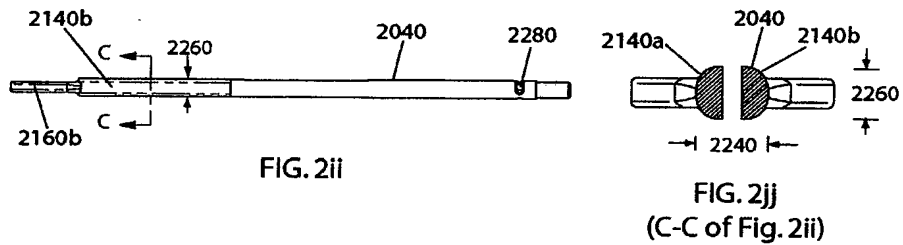
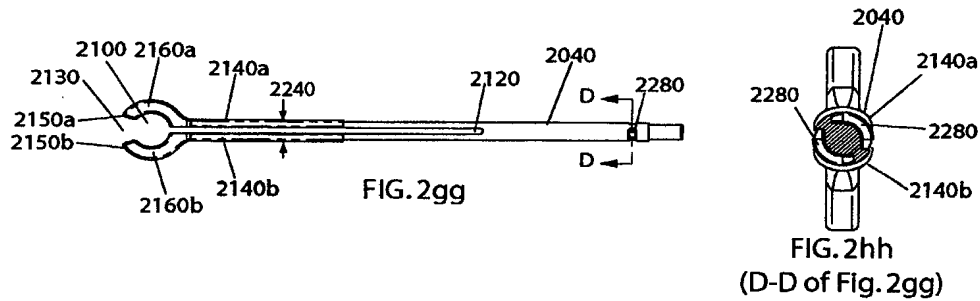
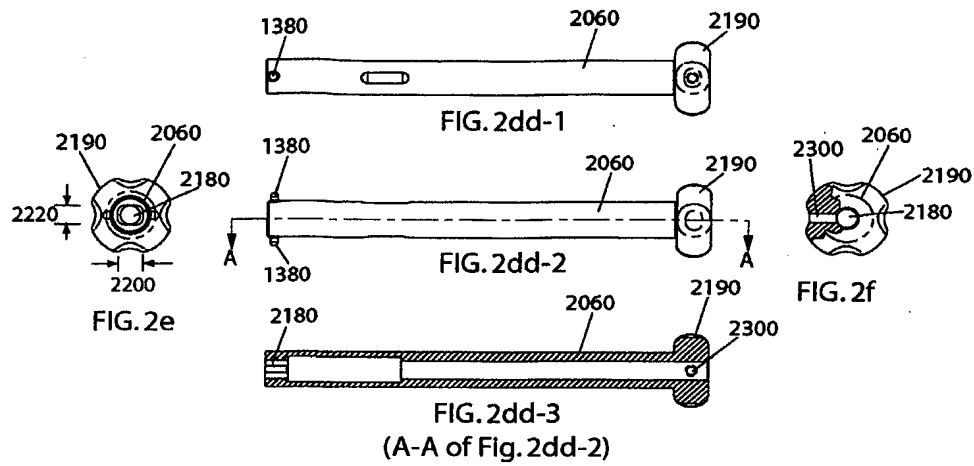
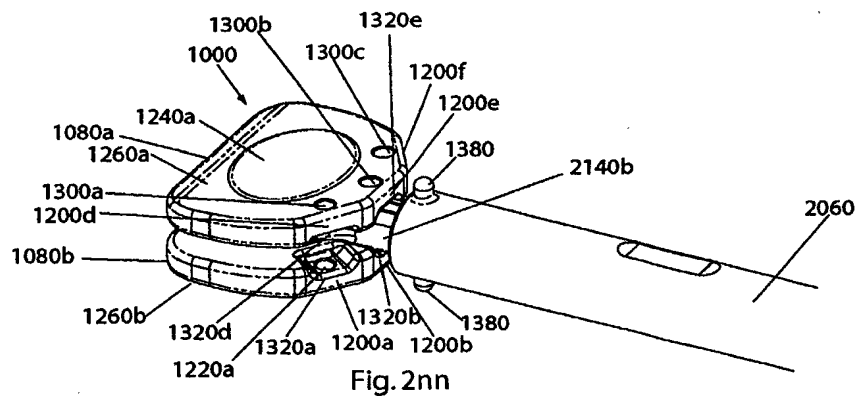
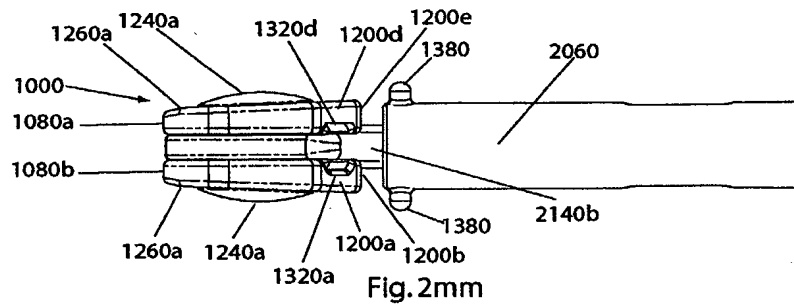
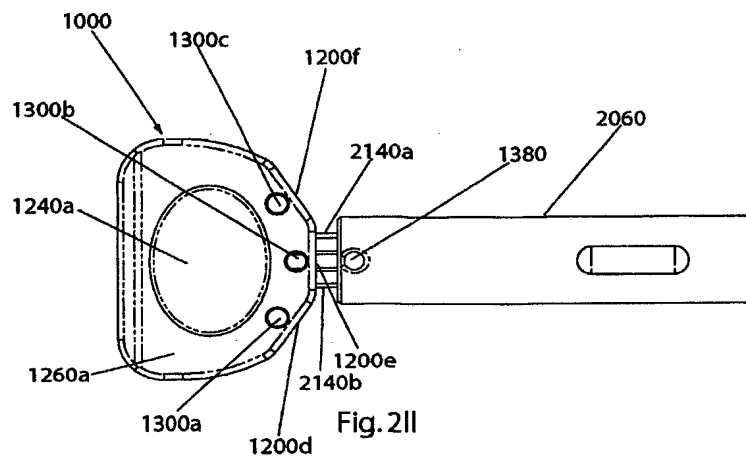
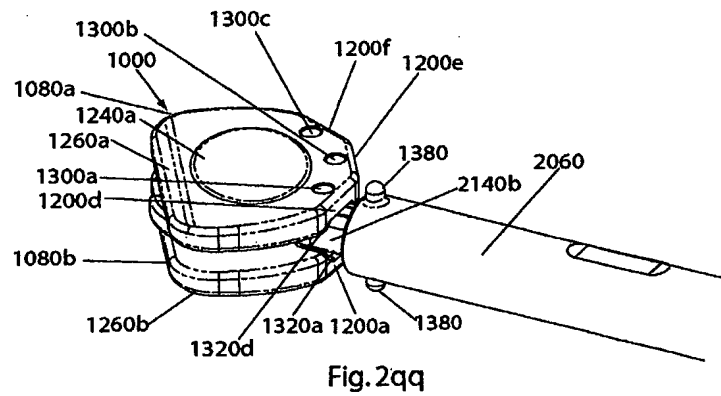
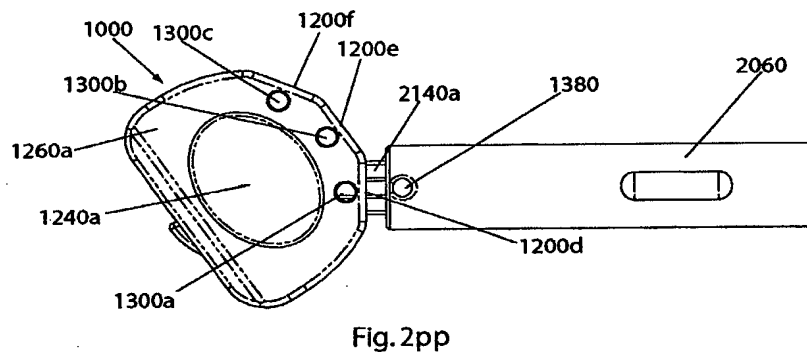
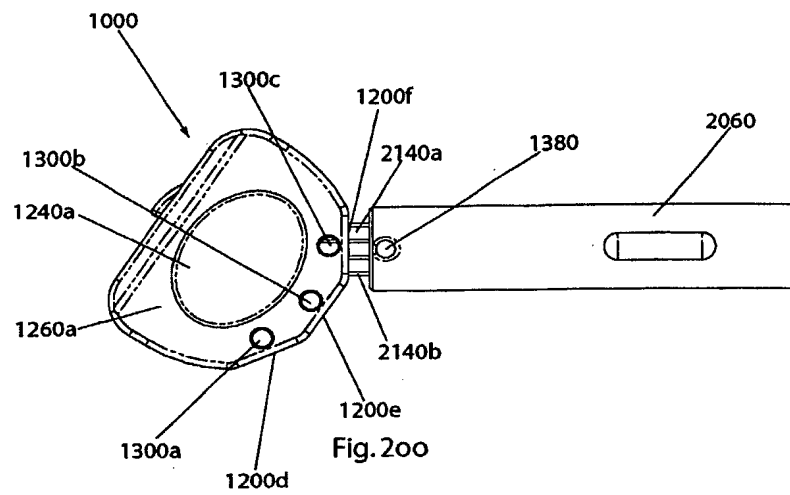
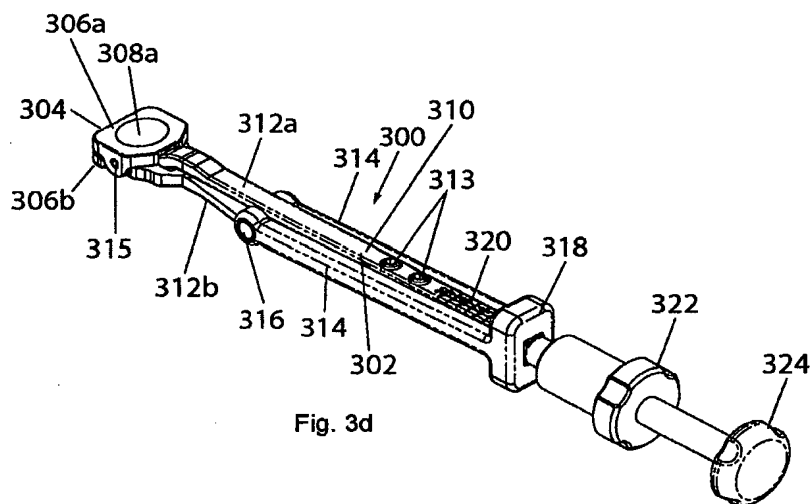
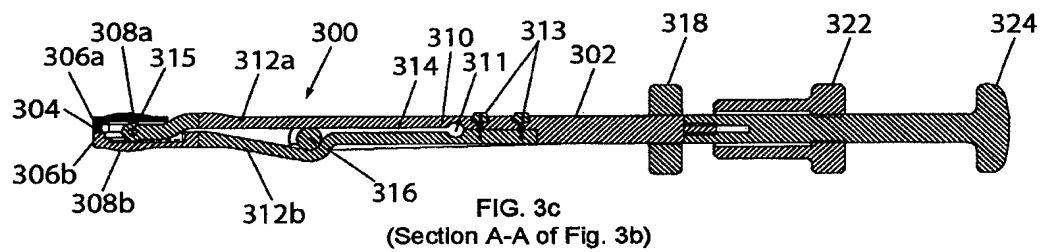
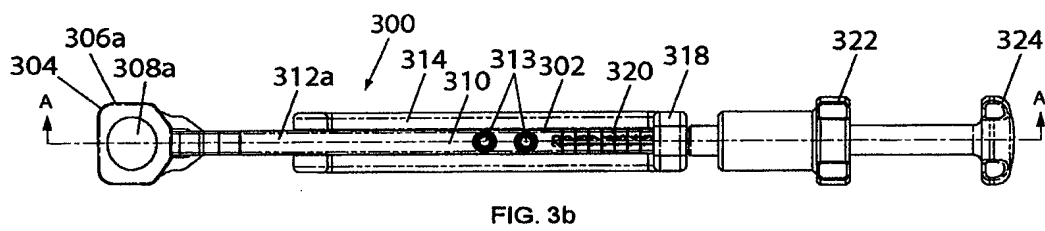
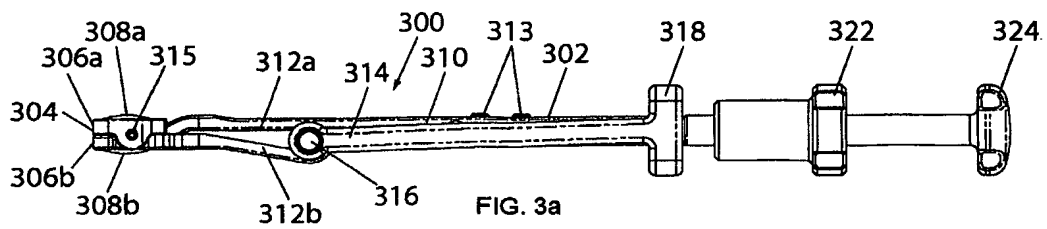


FIG. 2cc









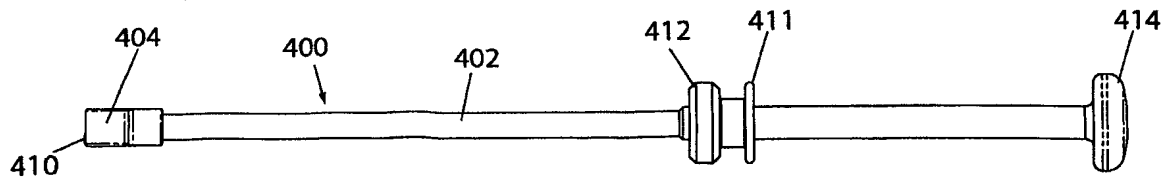


FIG. 4a

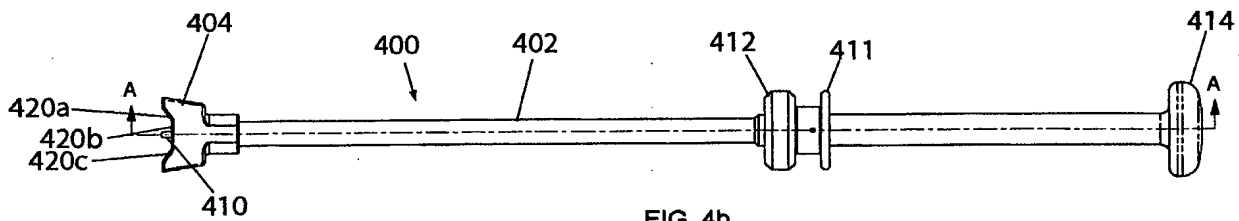


FIG. 4b

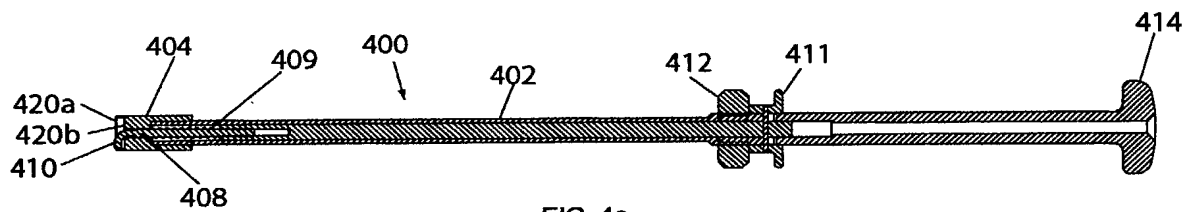


FIG. 4c
(Section A-A of Fig. 4b)

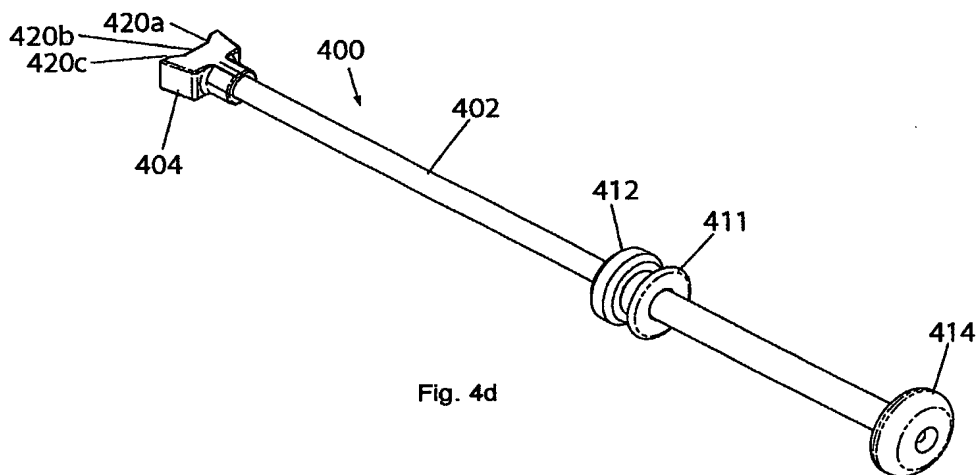


Fig. 4d

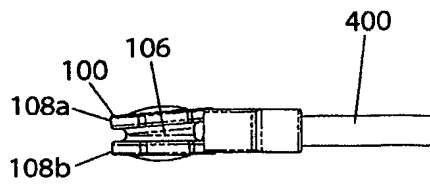


FIG. 4e

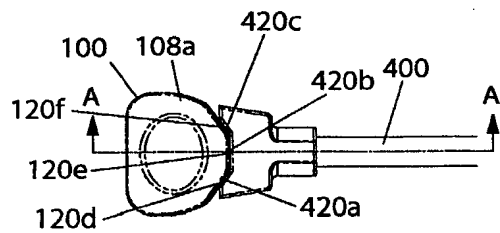


FIG. 4f

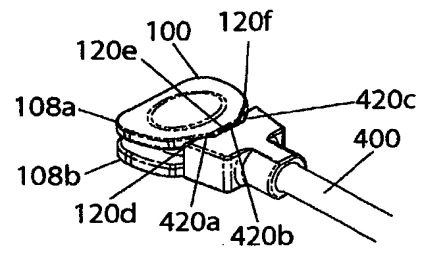


FIG. 4h

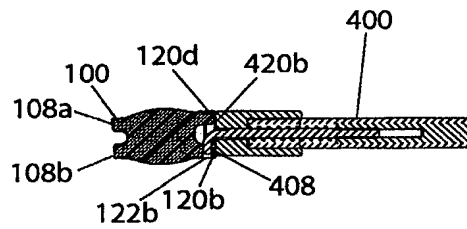


FIG. 4g

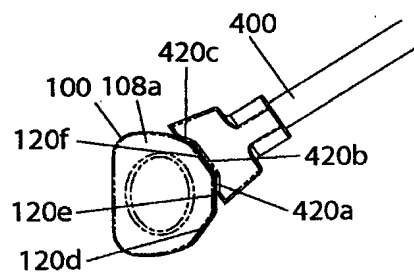


FIG. 4i

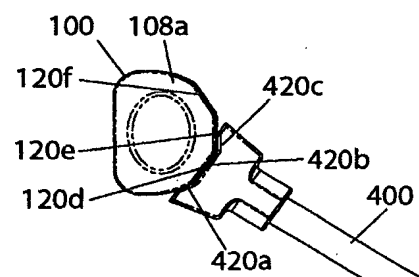


FIG. 4j

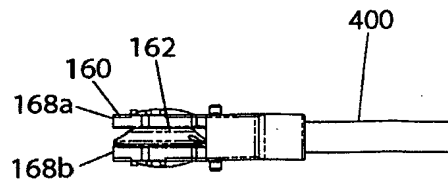


FIG. 4k

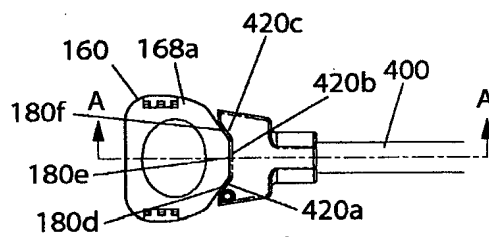


FIG. 4l

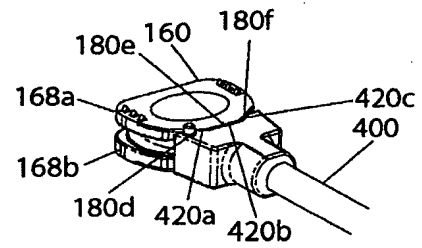


FIG. 4n

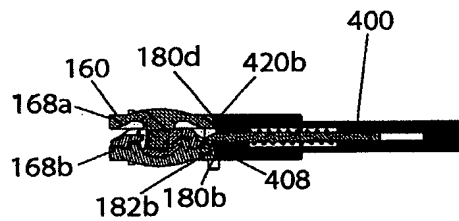


FIG. 4m

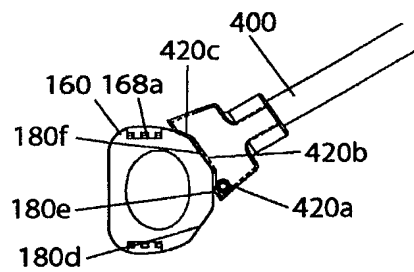


FIG. 4o

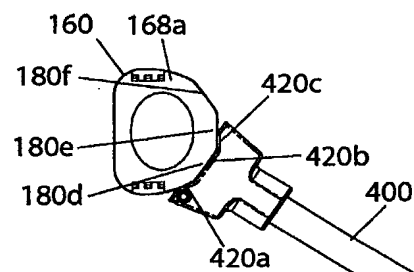


FIG. 4p

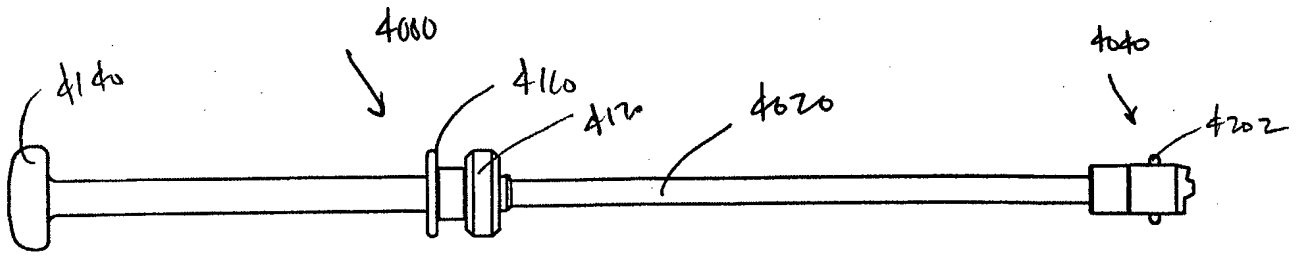


FIG. 4aa

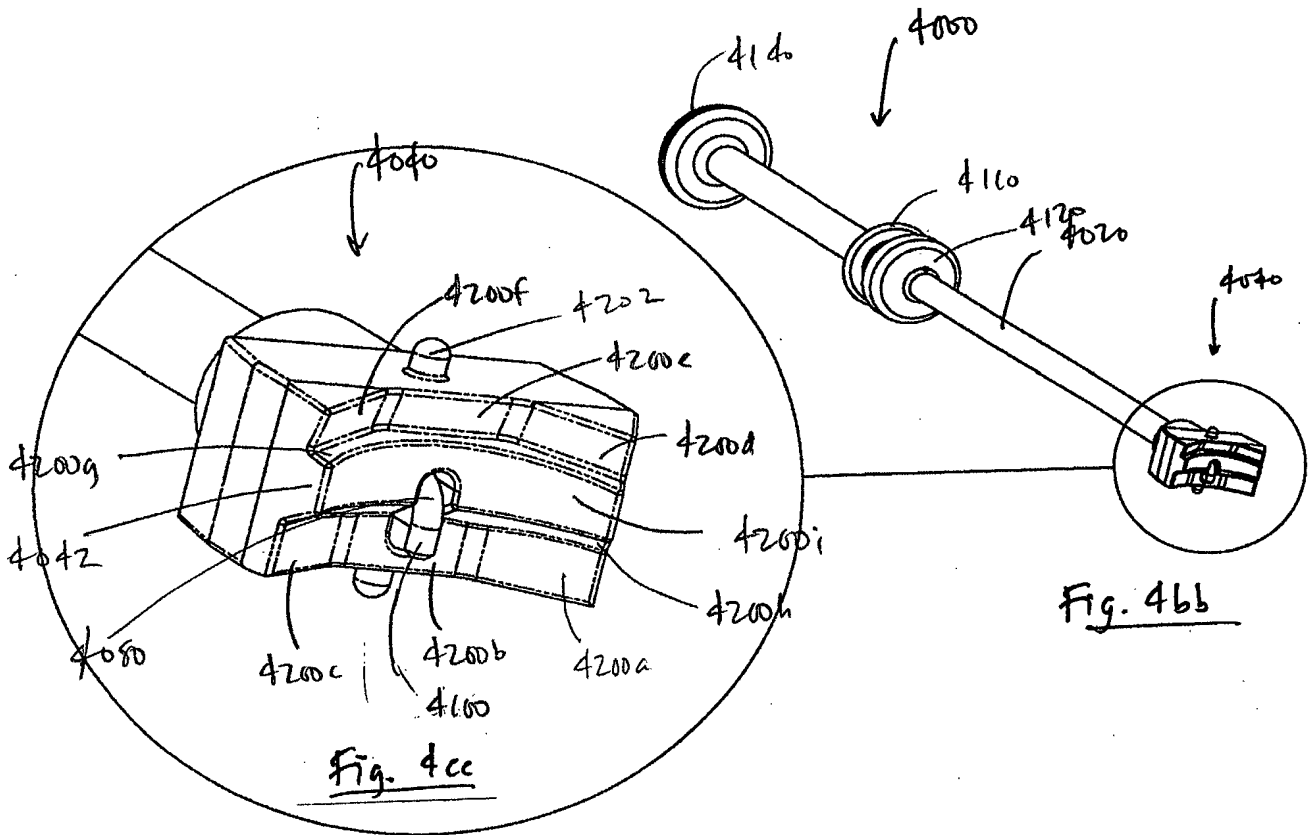
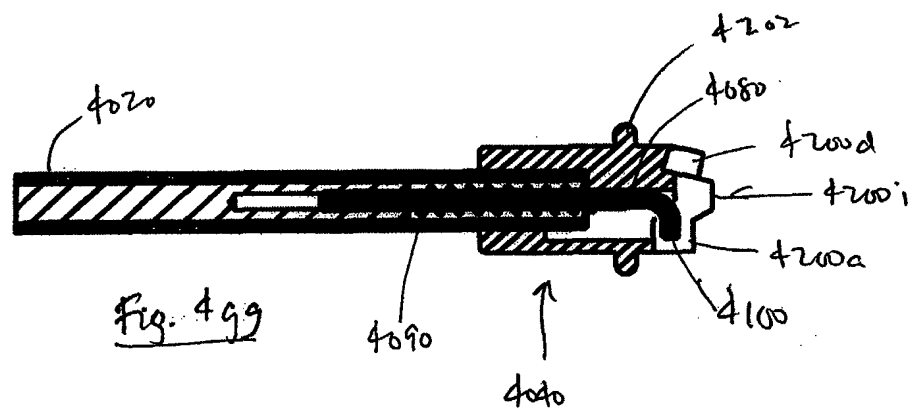
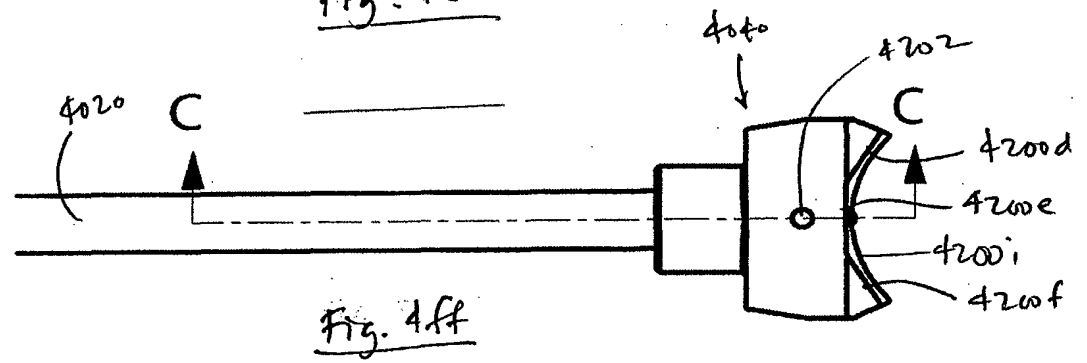
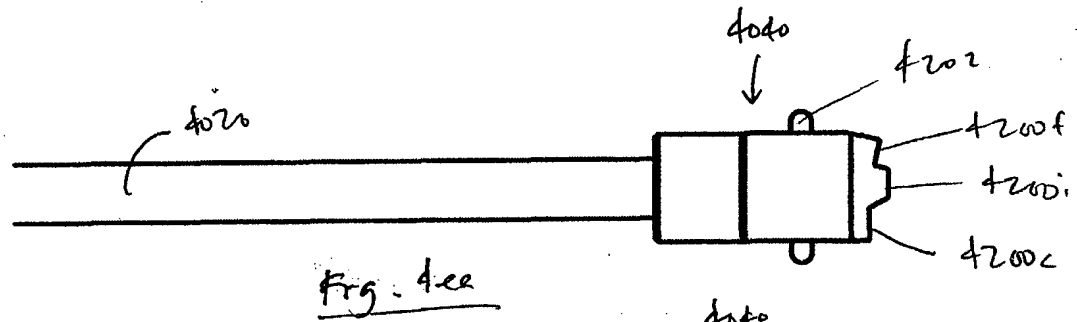
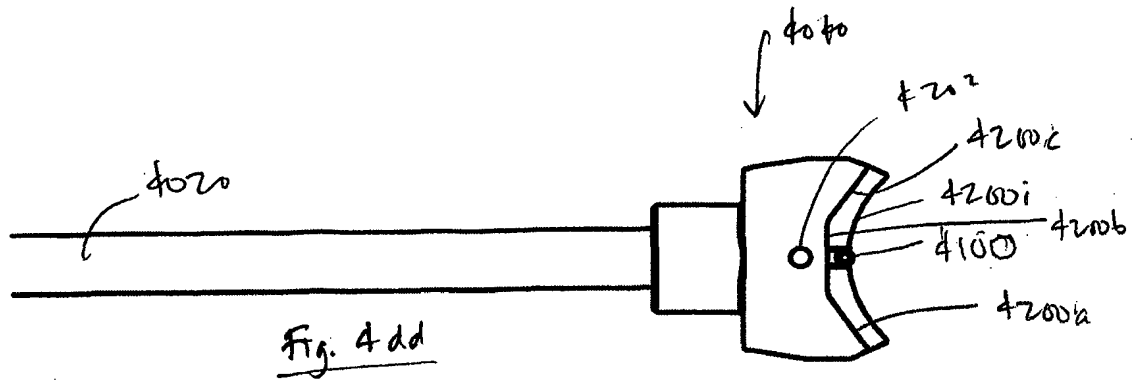
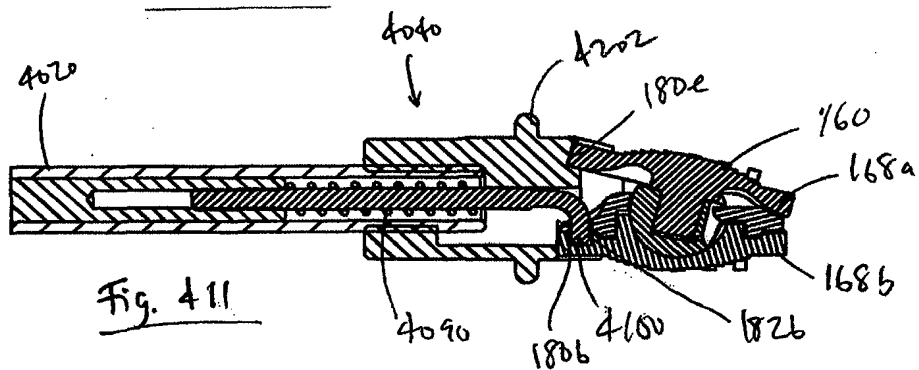
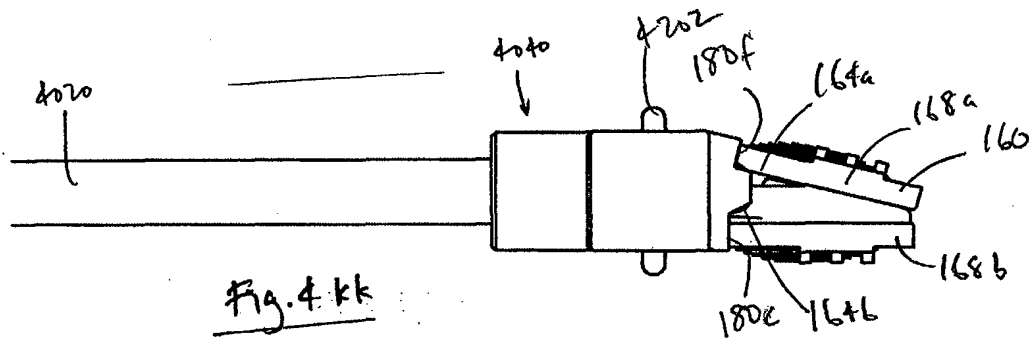
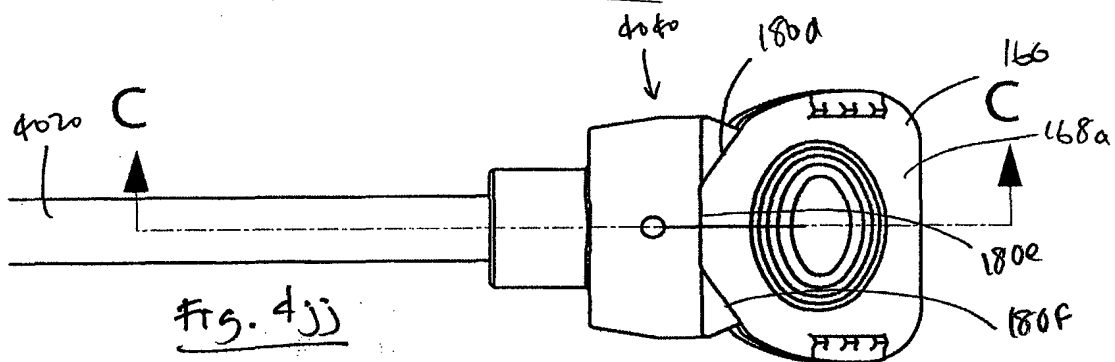
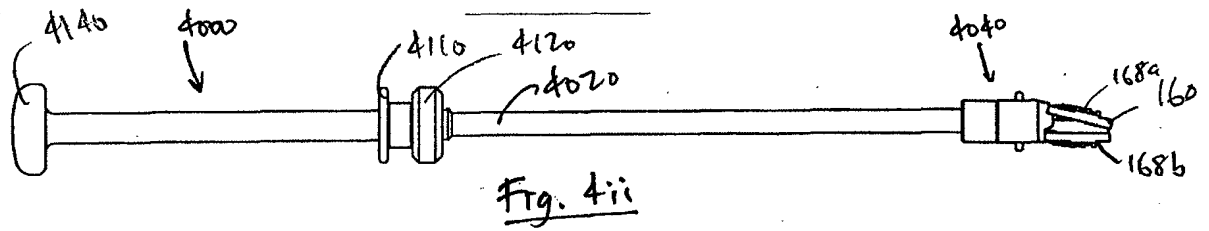
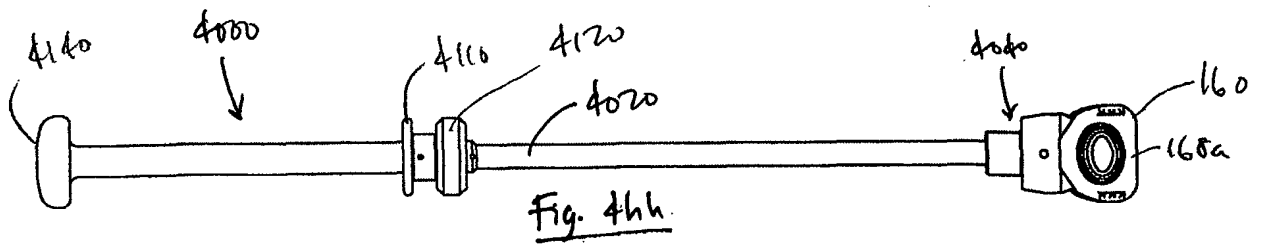
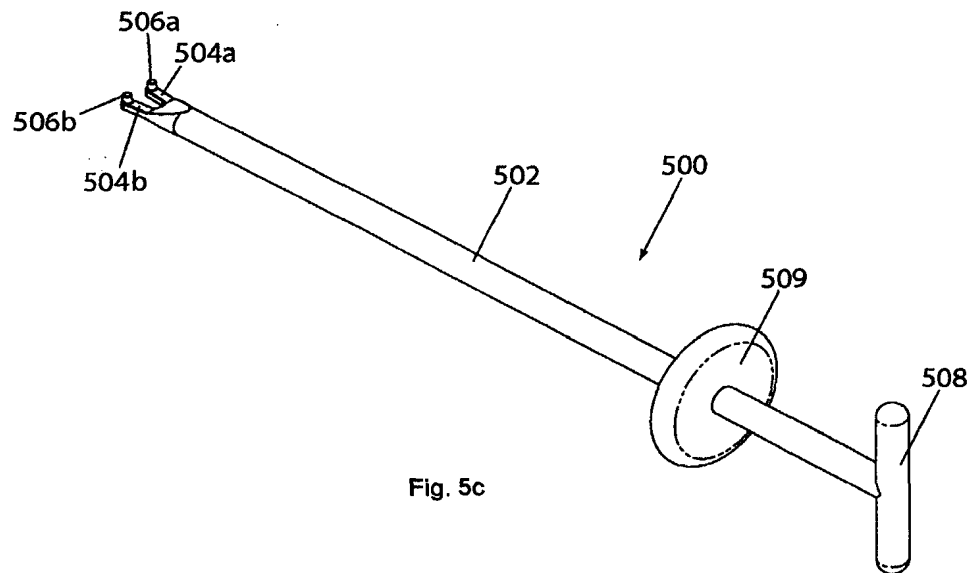
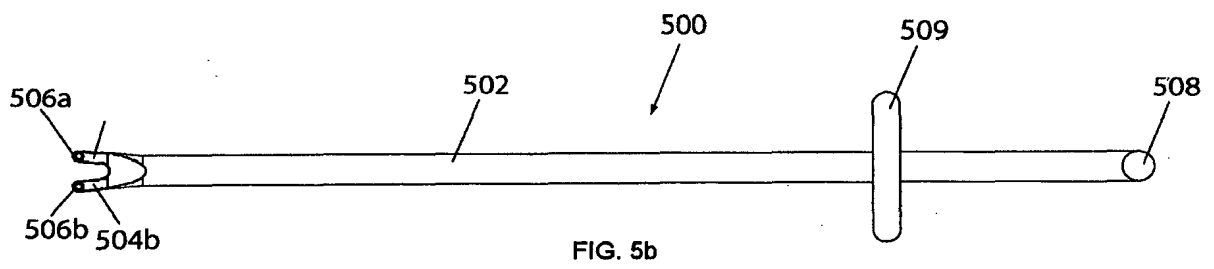
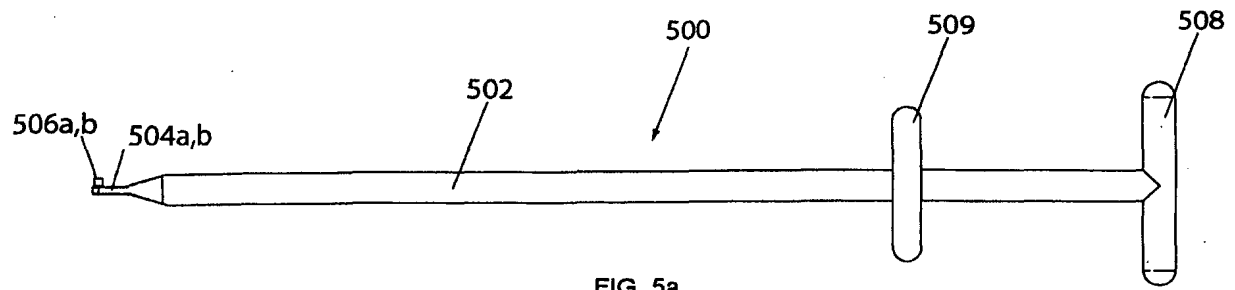


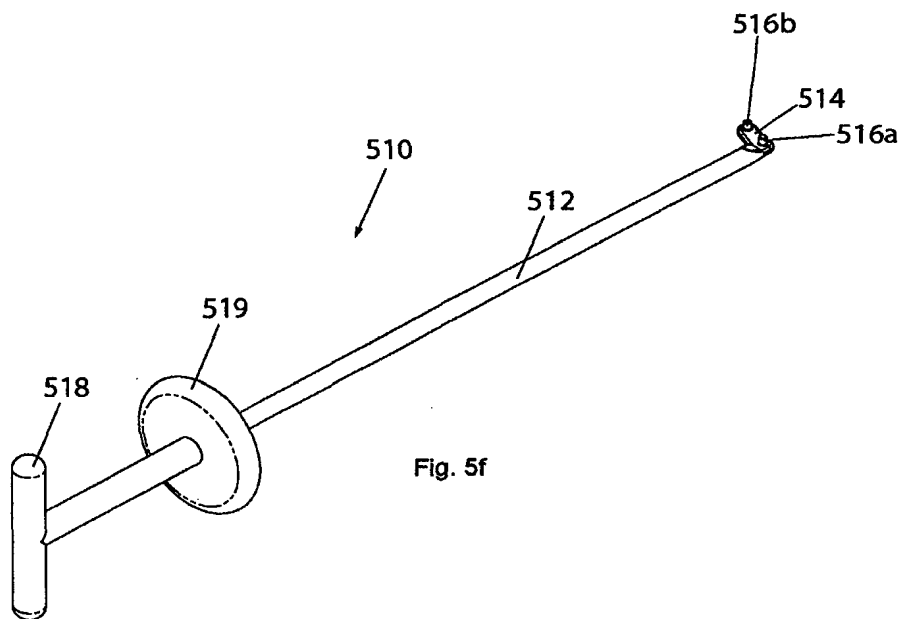
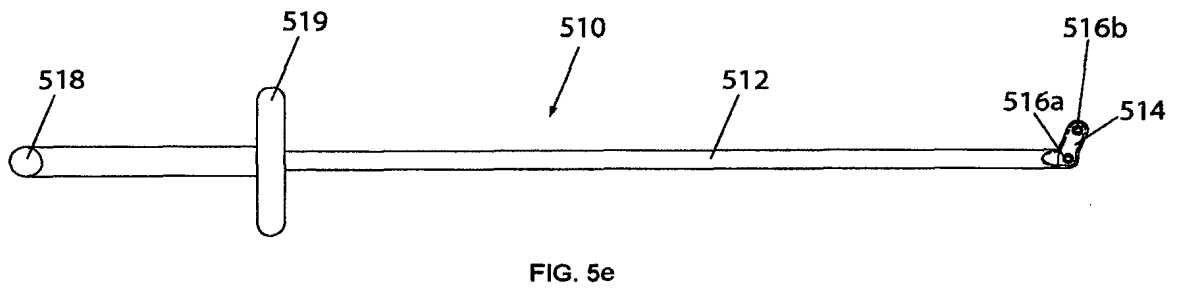
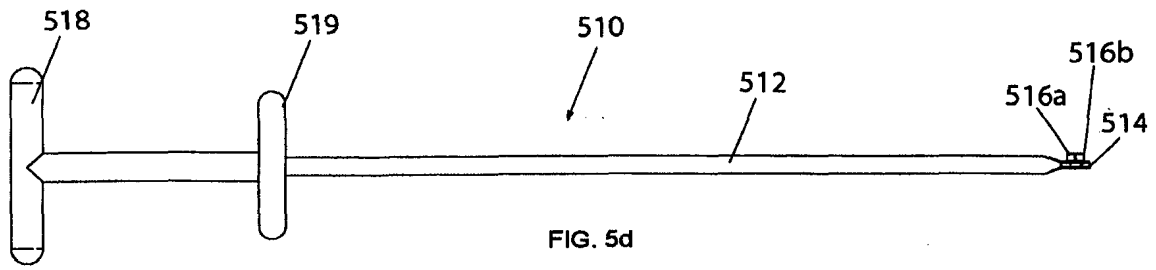
Fig. 4bb

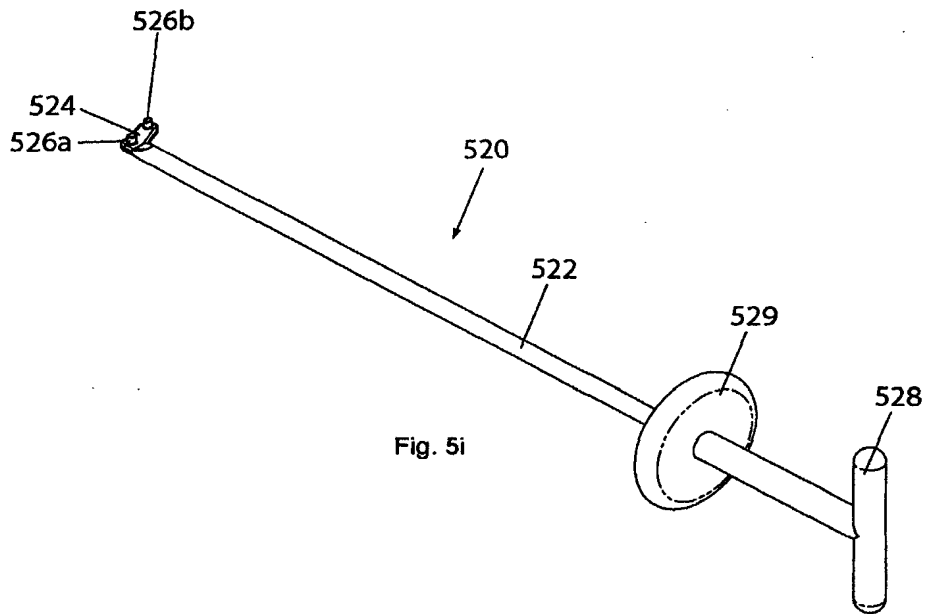
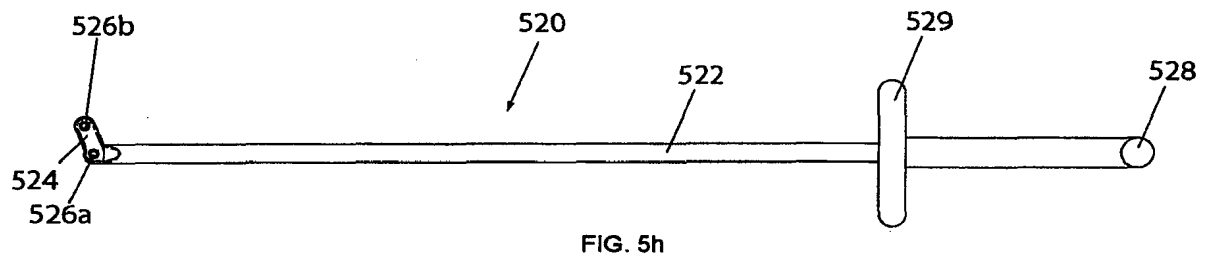
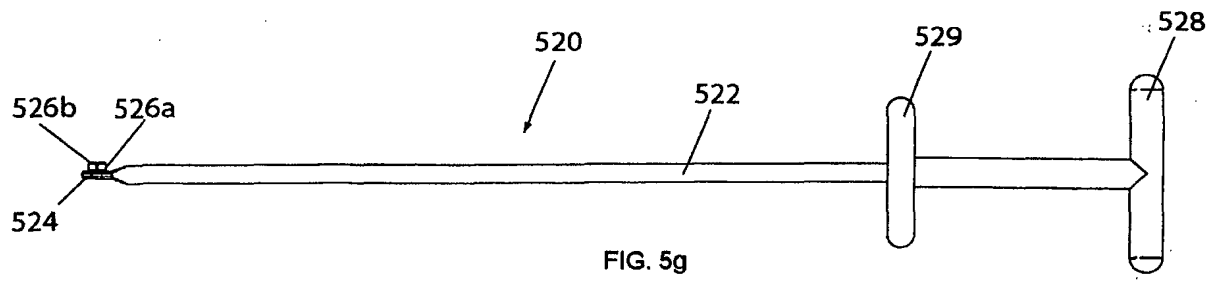
Fig. 4cc

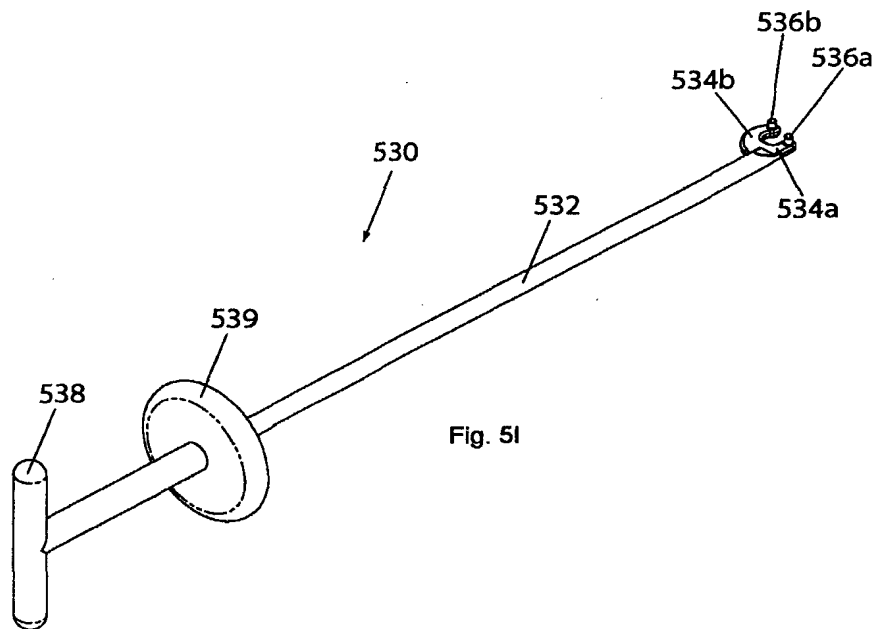
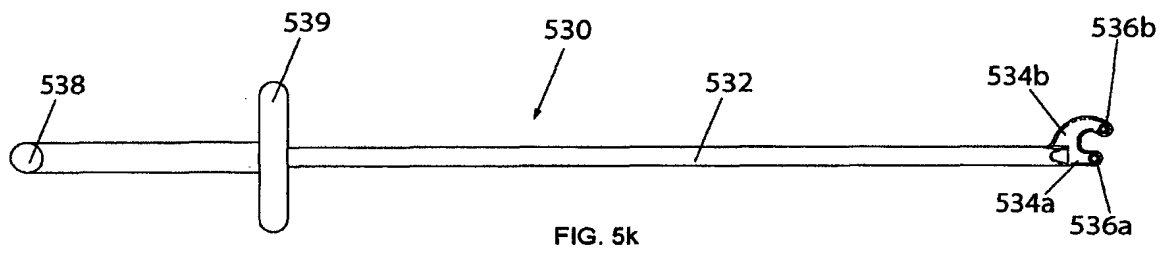
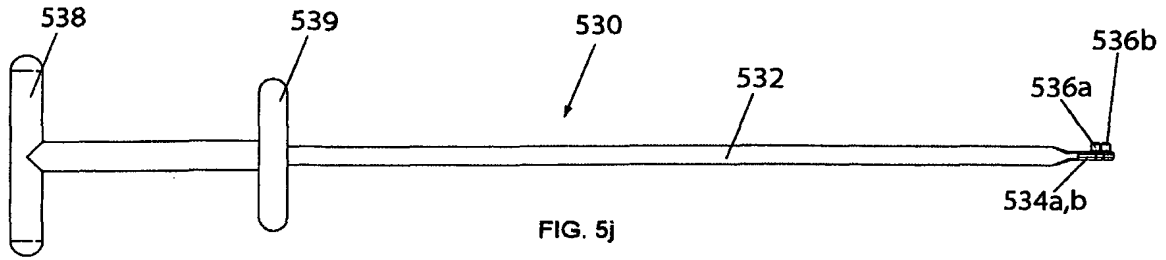


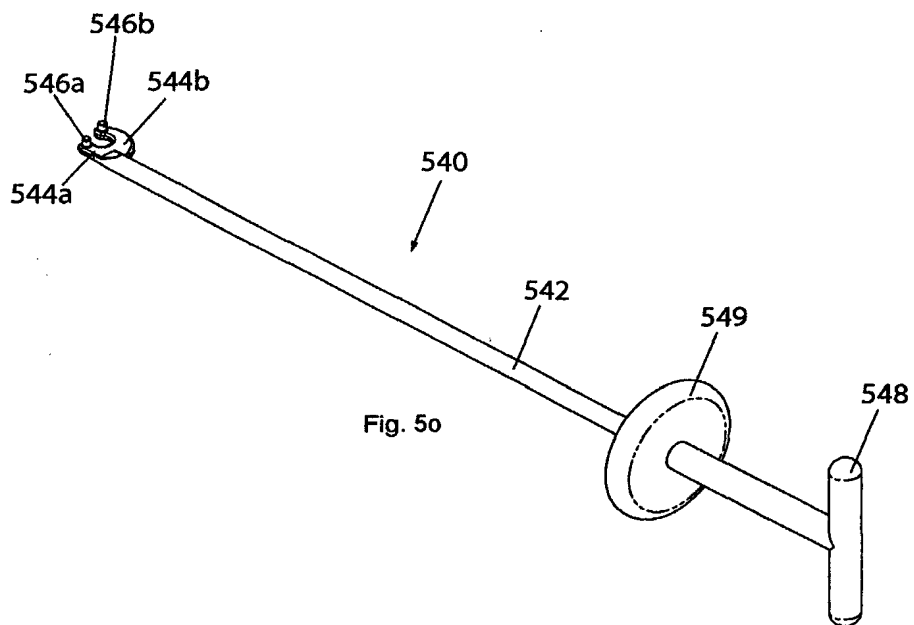
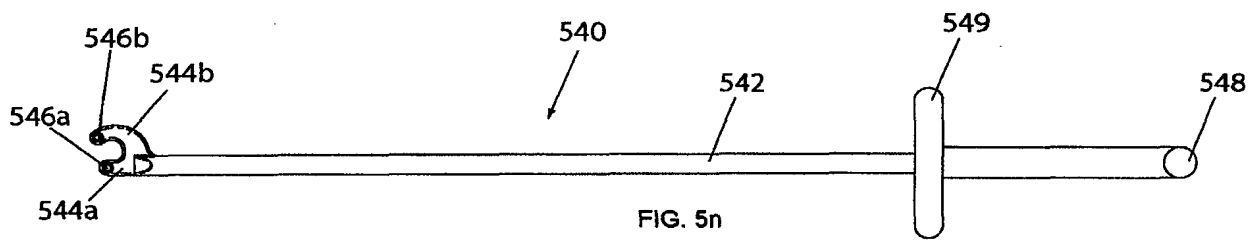
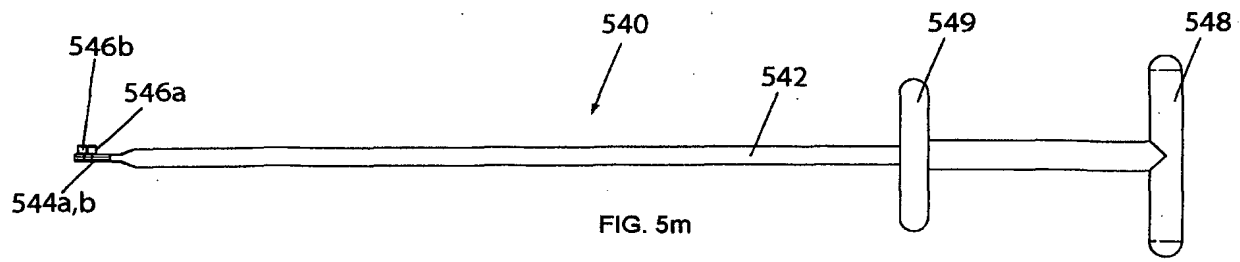












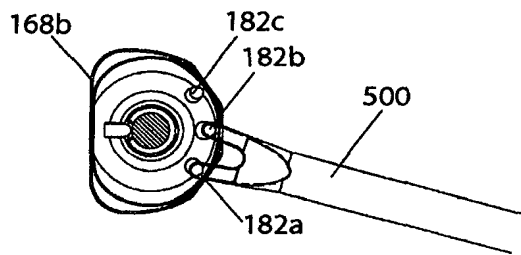


FIG. 5p

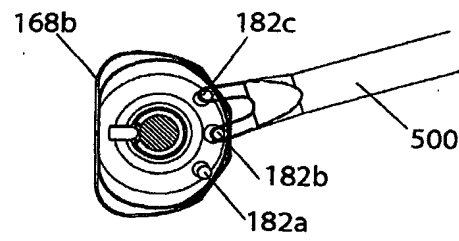


FIG. 5q

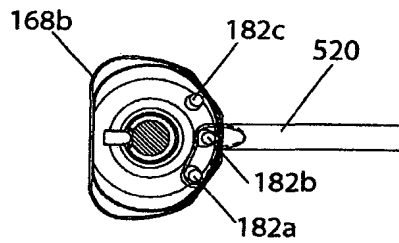


FIG. 5r

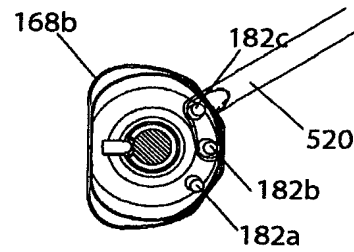


FIG. 5s

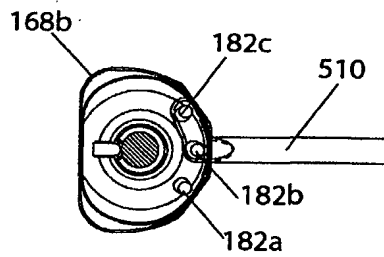


FIG. 5t

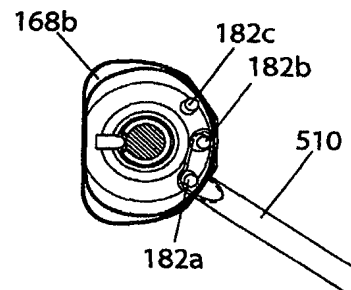


FIG. 5u

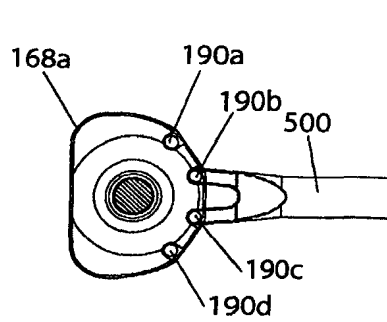


FIG. 5v

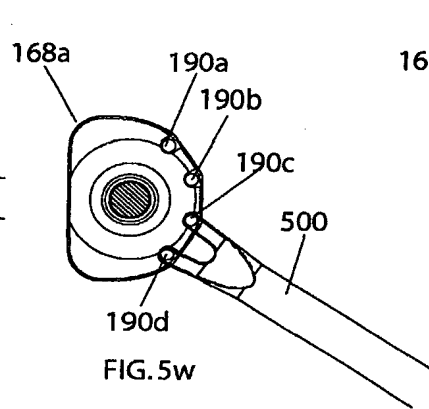


FIG. 5w

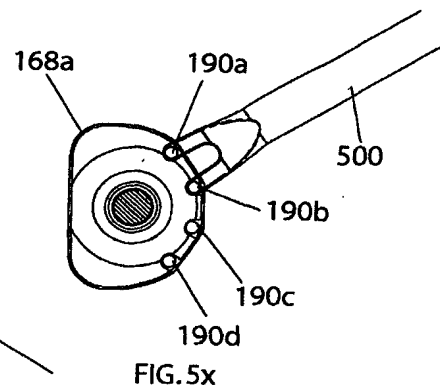


FIG. 5x

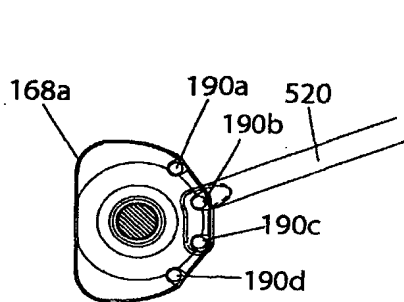


FIG. 5y

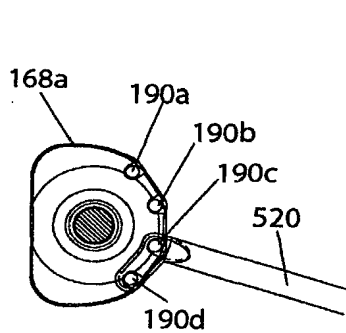


FIG. 5z

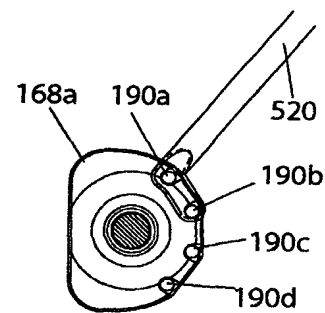


FIG. 5aa

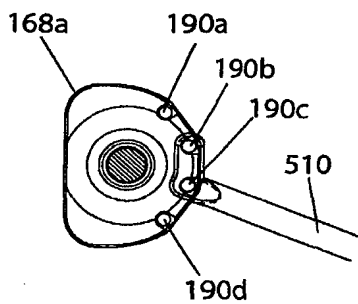


FIG. 5bb

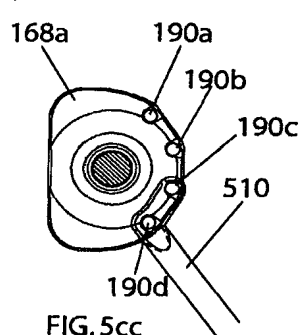


FIG. 5cc

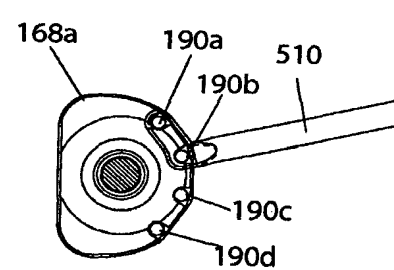
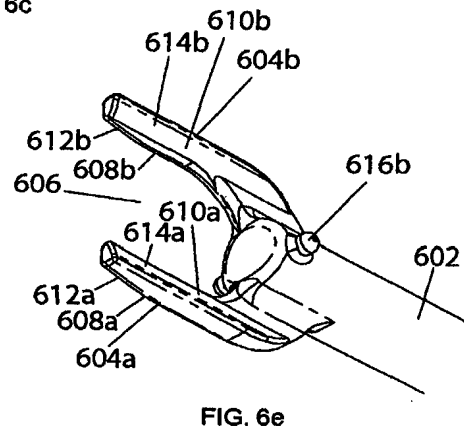
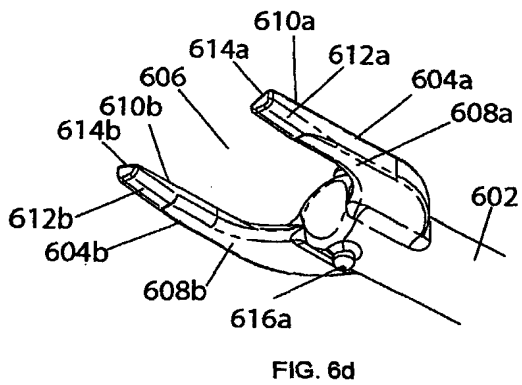
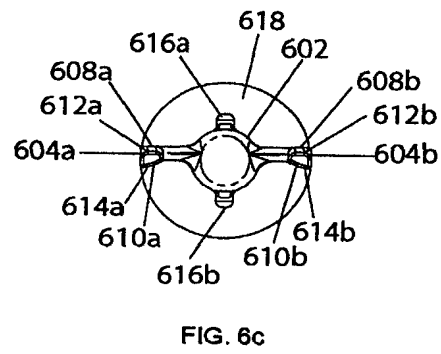
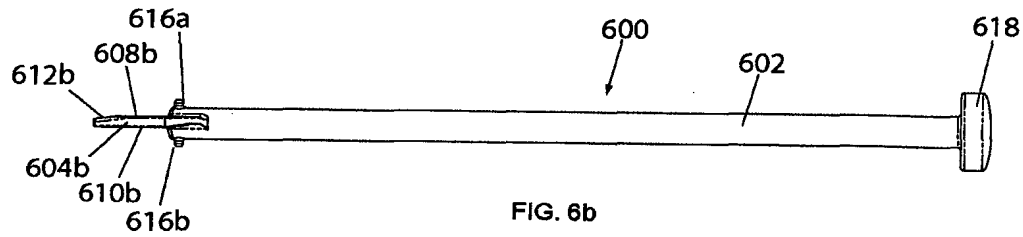
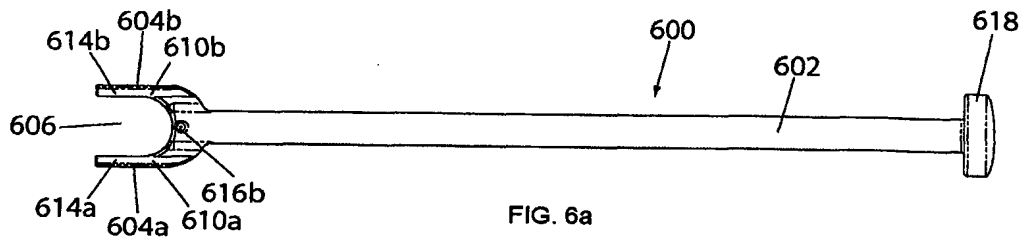


FIG. 5dd



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/28957

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44

US CL : 623/17.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.15,17.14;606/61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,436,102 B1 (Ralph et al) 20 August 2002, Figs. 2b,5a,7a,8a.	99,101-104,106,107
Y	US 5,683,465 A (Shinn et al) 04 November 1997, Fig. 2, col. 2, lines 26-29.	1,2,,5,8,11-14,16,20-25,27,28,37-41,44-46,49,50,77,99,101-104,106,107
X	US 5,314,477 A (Marnay) 24 May 1994, Figs. 1,10,11, col. 2, lines 26-40.	77-82,90,94,95
A	US 5,556,431 A (Buttner-Janz) 17 September 1996, Figs. 1,4.	83-89,91-93,96-98,100,105,108
Y	US 6,159,211 A (Boriani et al) 12 December 2000, Figs. 5,6.	1,2,5,8,11-14,16,19,20-25,27,28,37-41,44-46,49,50
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A		15,17,18,26,29-36

☒ Further documents are listed in the continuation of Box C.



See patent family annex.

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

02 January 2004 (02.01.2004)

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INTERNATIONAL SEARCH REPORT

PCT/US03/28957

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 6,261,296 B1 (Aebi et al) 17 July 2001, Figs. 1-3,5,12-16.	1,2,5,8,11- 14,16,19,20- 25,27,28,37-41,44- 46,49,50 ----- 3,4,6,7,9,10,42,43,47 ,48,51-63

INTERNATIONAL SEARCH REPORT

Continuation of B. FIELDS SEARCHED Item 3:

EAST search terms:

tool, plates, moveable, rotatable, articulates, positioner

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(10) International Publication Number
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(21) International Application Number:
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(22) International Filing Date: 31 October 2003 (31.10.2003)

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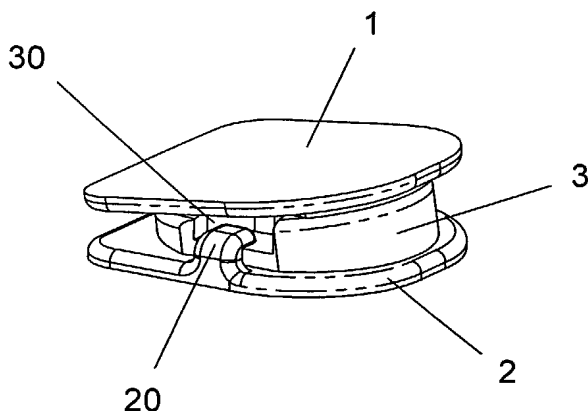
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL DISK PROSTHESIS



(57) Abstract: The present invention relates to an intervertebral disk prosthesis comprising at least three parts including a first plate, referred to as the upper plate (1), a second plate, referred to as the lower plate (2), and a core (3), the upper surface of the core (3) being in contact with at least part (10) of the lower surface of the upper plate (1) and the lower surface of the core (3) being in contact with at least part of the upper surface of the lower plate (2), and the lower plate (1) being movable at least with respect to the core (3), characterised in that there are cooperation means between the lower to plate (2) and the core (3), so as to limit or eliminate translation movements of the core (3) with respect to the lower plate (2) along an axis substantially parallel to the lower plate (2), and to limit or eliminate rotation movements of the core (3) with respect to the lower plate (2), around an axis substantially perpendicular to the lower plate (2), the planes passing

through the upper (1) is and lower (2) plates forming a substantially constant angle.

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INTERVERTEBRAL DISK PROSTHESIS

The present invention relates to an intervertebral disk prosthesis, intended to substitute the fibrocartilaginous disks joining the vertebrae in the spinal column, particularly on the cervical spine.

Various types of prosthesis are known in the prior art. Some of these prostheses, either because they are made of compressible material or because they allow excessive movement of the different constituent parts of the prosthesis with respect to each other, may induce relatively easily the ejection of at least one part of the prosthesis outside the vertebrae, which is not desirable for the patient.

The purpose of the present invention is to remedy some drawbacks of the prior art by proposing a simple intervertebral disk prosthesis which makes it possible to limit the movements of the different constituent parts of the prosthesis with respect to each other.

This purpose is achieved by an intervertebral disk prosthesis comprising at least three parts including a first plate, referred to as the upper plate, a second plate, referred to as the lower plate, and a core, the upper surface of the core being in contact with at least part of the lower surface of the upper plate and the lower surface of the core being in contact with at least part of the upper surface of the lower plate, and the lower plate being movable at least with respect to the core, characterised in that there are cooperation means between the lower plate and the core, so as to limit or eliminate translation movements of the core with respect to the lower plate, along an axis substantially parallel to the lower plate, and to limit or eliminate rotation movements of the core with respect to the lower plate, around an axis substantially perpendicular to the lower plate, the planes passing through the upper and lower plates forming a substantially constant angle.

According to another feature, the lower plate comprises male means cooperating with female means of the core.

According to another feature, the lower plate comprises female means cooperating with male means of the core.

According to another feature, the angle is obtained in that the core forms an acute angle in the front-rear direction.

5 According to another feature, the same plates can be assembled with cores of different thicknesses.

According to another feature, the angle between the upper and lower plates is between 0° and 15°.

10 According to another feature the core is movable with respect to the upper and/or lower plates, which makes it possible to compensate for positioning defects of the three parts of the prosthesis with respect to each other.

According to another feature, at least part of the lower surface of the upper plate is concave and complementary to the upper surface of the core.

15 According to another feature, the dimensions of each male means are slightly less than those of each female means so as to enable a slight clearance between the core and the lower plate.

20 According to another feature, the dimensions of each male means are substantially the same as those of each female means so as to prevent any clearance between the core and the lower plate.

According to another feature, the male means of the lower plate are two pins curved towards the inside of the prosthesis and located opposite each other on two edges of the prosthesis, and in that the female means of the core are two recesses.

25 According to another feature, at least one of the pins is replaced by a lug equipped with a drilling whereon a tag is fixed using a dowel entering the drilling.

30 According to another feature, the male means of the lower plate are two dowel pins located in the vicinity of the centre of the lower plate, and in that the female means of the core are two wells.

According to another feature, the male means of the lower plate are two walls located opposite each other in the vicinity of two edges of the prosthesis, and in that the female means of the core are recesses.

5 According to another feature, the male means of the lower plate are a rib located at the centre of the prosthesis, and in that the female means of the core are a groove.

According to another feature, the core is made of polyethylene.

10 According to another feature, the lower plate comprises one or more openings in the vicinity of its front side, provided to receive prosthesis anchoring means in a vertebra.

According to another feature, the opening of the lower plate is rectangular, and in that the anchoring means consist of a body, forming an acute angle with the lower plate, and a head.

15 According to another feature, the openings of the lower plate are circular, and in that the anchoring means are nail-shaped.

According to another feature, the upper plate is convex on at least part of its upper surface to fit into the shape of the vertebrae.

20 Other features and advantages of the present invention will be seen more clearly upon reading the description below, with reference to the appended figures, wherein:

- figures 1a and 1b respectively represent a bottom view and a perspective bottom view of the upper plate according to one embodiment,

- figures 2a and 2b respectively represent a top view and a perspective top view of the lower plate according to one embodiment,

25 - figures 3a and 3b respectively represent a top view and a perspective top view of the core according to one embodiment,

- figures 4a and 4b respectively represent a perspective top view and a side view of the intervertebral disk prosthesis according to the embodiment of figures 1a, 1b, 2a, 2b, 3a and 3b,

30 - figures 5a and 5b respectively represent a side view and a sectional view along the plane D-D of figure 5a of the intervertebral disk prosthesis according to a second embodiment,

- figure 6a represents a side view of the intervertebral disk prosthesis according to a third embodiment,

- figures 6b and 6d represent a sectional view along the plane A-A of figure 6a, the core having, respectively, a slight clearance and no clearance with respect to the lower plate,

- figures 6c and 6e represent a sectional view along the plane B-B of figure 6b and 6d, respectively, of the intervertebral disk prosthesis,

- figures 7a and 8a respectively represent a top view and perspective bottom view of the lower plate according to two other embodiments,

- figures 7b and 8b respectively represent a perspective side view and a perspective top view of the lower plate of figures 7a and 8a, respectively, wherein prosthesis anchoring means are inserted according to two different embodiments,

- figure 9a represents a top view of the lower plate according to a fourth embodiment,

- figure 9b represents a sectional view of the lower plate along the plane plan C-C of figure 9a,

- figures 10a and 10b respectively represent a rear and side view of the upper plate according to another embodiment.

The intervertebral disk prosthesis according to the invention is constituted of an upper plate 1 which is articulated with respect to a lower plate 2 by means of a core 3, as can particularly be seen in figures 4a, 4b, 5a and 6a. One advantage of the prosthesis according to the invention is that it comprises simple parts which can be designed so that the prosthesis is fitted on the cervical spine.

The upper plate 1, particularly visible in figures 1a and 1b, is slightly concave on at least part 10 of its lower surface, so as to fit with the slightly convex upper surface of the core 3. The upper surface of the core 3 is complementary to the concave part 10 of the upper plate 1, enabling movement between the upper plate 1 and the core 3.

In an alternative embodiment, part of the upper surface of the upper plate 1 is convex, as shown in figures 10a and 10b, in order to fit better onto

the vertebra whereon the prosthesis is to be fitted, the bottom of the vertebrae being concave. In this case, the convex part of the upper plate 1 is located in the front part of the upper plate, as can particularly be seen in figure 10b.

5 The lower plate 2 is substantially plane. In effect, its lower surface does not need to be convex or concave since the top of the vertebrae is substantially flat. In the embodiment of figures 2a, 2b, 7a and 8a, the lower plate 2 comprises two pins 20 located opposite each other on two substantially parallel edges 21, 22 of the lower plate 2. Each pin 20 is curved
10 towards the inside of the prosthesis and can thus enter recesses 30 located on the core 3. The core 3, particularly visible in figures 3a and 3b, comprises a substantially plane lower surface, provided to fit onto the lower plate 2. The core 3 is thin (for example 3 mm thick) for a cervical prosthesis or thicker (for example 15 mm) for a lumbar prosthesis.

15 In the embodiment of figures 3a, 3b, 4a and 4b, the dimensions of each recess 30 of the core 3 are slightly greater than those of each pin 20 of the lower plate 2 so as to limit the clearance of the core 3 with respect to the lower plate 2, both in translation along an axis substantially parallel with the lower plate 2, and in rotation around an axis substantially perpendicular to
20 the lower plate 2. The movement between the upper plate 1 and the core 3, as well as the clearance of the core 3 with respect to the lower plate 2, thus enable the patient to move and, if required, compensate for prosthesis positioning defects. This clearance also offers the advantage of preventing premature wear due to the stress applied to the prosthesis.

25 In the embodiment of figures 5a and 5b, the dimensions of each recess 30 of the core 3 are substantially the same as those of each pin 20 of the lower plate 2, so as to prevent any clearance of the core 3 with respect to the lower plate 2, both in translation and rotation. In the latter case, the only movement of the prosthesis authorised is that of the upper plate 1 with
30 respect to the core 3.

 In the embodiment in figures 9a and 9b, one of the pins 20 is replaced by a lug equipped with a drilling 200. A tag 23 fixes on the lug by means of a

dowel 24 entering the drilling 200. In an alternative embodiment, both pins are replaced by a lug whereon a tag 23 is fixed.

In the embodiment of figures 6a, 6b, 6c, 6d and 6e, the lower plate 2 does not comprise any pins 20 but two dowel pins 25 located in the vicinity of the centre of the lower plate 2. In this case, the core 3, by complementarity, does not comprise any recesses 30, but two wells 35 under its lower surface. The dimensions of the dowel pins 25 of the lower plate 2 and of the wells 35 of the core 3 are such that, in the alternative embodiment represented in figures 6b and 6c, a slight clearance in translation and rotation is permitted, and in the alternative embodiment represented in figures 6d and 6e, no clearance is permitted.

In another embodiment, not shown, the lower plate 2 comprises a rib on its upper surface and no pins 20 or dowel pins 25. The core 3, by complementarity, comprises a groove under its lower surface. The dimensions of the rib of the lower plate and the groove of the core are such that, in one alternative embodiment, a slight clearance in translation and rotation is permitted, and in another alternative embodiment, no clearance is permitted.

In another embodiment not shown, the lower plate 2 comprises, instead of the pins 20, two walls, arranged opposite each other, in the vicinity of two substantially parallel edges 21, 22 of the lower plate, but further in the prosthesis than the pins 20. The core 3 comprises complementary recesses with respect to the walls. The dimensions of each recess of the core in this embodiment are, either slightly greater, or substantially the same as those of each wall of the lower plate, so as to enable a slight clearance in translation and rotation or not.

In a further embodiment not shown, the female components are located on the lower plate and the male components on the core.

The intervertebral disk prosthesis according to the invention particularly makes it possible to correct lordosis defects and to add lordosis to the spine, for example the cervical spine. Therefore, the presence of an acute angle in the front-rear direction F, figure 4b, between the upper plate 1

and the lower plate 2 of the prosthesis is necessary. For example, this angle is between 0° and 15°. To adjust the angle required according to the patient, it is simply necessary to select a core 3 with a suitable angle between the mean plane representing its upper surface and the plane passing through its lower surface.

When the female components are located on the lower plates and the male components on the core, the lordotic core, in that it forms an acute angle in the front-rear direction, may then be integral with the plate by a projection entering a cavity or opening of the lower plate.

The inclination of the prostheses known in the prior art is obtained, either by the shape of the upper plate, when the core is flat, or by the position of the upper plate with respect to the core, when said core is convex. With respect to the first case of the prior art mentioned here, the machining of the prosthesis according to the present invention is more economical since the core is composed of a less expensive material (for example, polyethylene) than that composing the plates. With respect to the second case of the prior art mentioned here, the core of the present invention is not liable to be ejected outside the prosthesis since the angle between the plates is substantially constant when the prosthesis is in place.

If surgeons require a determined lordosis for one patient, they will select a core 3 allowing no clearance with respect to the lower plate 2. On the other hand, if they simply require the lordosis to remain within a range of values, they will select a core allowing a slight clearance in translation and rotation with respect to the lower plate 2.

The intervertebral disk prosthesis according to the invention may, in one alternative embodiment, represented in figures 7a, 7b, 8a and 8b, be anchored in the spinal column to prevent the prosthesis from migrating under the effect of the transversal resultant of the force exerted by the spinal column on the prosthesis in place, which increases with the lordosis. In this case, the lower plate 2 comprises one or more openings 28, 29 located in the vicinity of the rear side of the prosthesis, making it possible to receive anchoring means 4, 5.

In this way, in the case of figures 7a and 7b, the opening 28 of the lower plate 2 is rectangular and the anchoring means 4 is constituted of a body 40 and a head 41. The dimensions of the head 41 are slightly greater than those of the opening 28 of the lower plate 2, such that, once the
5 anchoring means 4 are in place in a vertebra, the lower plate 2 is sandwiched between the head 41 of the anchoring means 4 and said vertebra. An angle, less than or equal to 90° , is comprised between the body 40 of the anchoring means 4 and the lower plate 2.

In the case of figures 8a and 8b, two circular openings 29 are
10 comprised in the lower plate 2 and the anchoring means 5 are nail-shaped, with a head of greater dimensions than those of the openings 29 to make it possible to sandwich the lower plate 2 between the head of the anchoring means 5 and the vertebra whereon the prosthesis is anchored.

It should be clear to those skilled in art that the present invention
15 enables embodiments in numerous other specific forms without deviating from the scope of the invention as claimed. Consequently, the present embodiments must be considered as illustrations, but may be modified in the field defined by the scope of the attached claims, and the invention must not be limited to the details given above.

CLAIMS

1. Intervertebral disk prosthesis comprising at least three parts including a first plate, referred to as the upper plate (1), a second plate, referred to as the lower plate (2), and a core (3), the upper surface of the core (3) being in contact with at least part (10) of the lower surface of the upper plate (1) and the lower surface of the core (3) being in contact with at least part of the upper surface of the lower plate (2), and the upper plate (1) being movable at least with respect to the core (3), characterised in that there are cooperation means between the lower plate (2) and the core (3), so as to limit or eliminate translation movements of the core (3) with respect to the lower plate (2) along an axis substantially parallel to the lower plate (2), and to limit or eliminate rotation movements of the core (3) with respect to the lower plate (2), around an axis substantially perpendicular to the lower plate (2), the planes passing through the upper (1) and lower (2) plates forming a substantially constant angle.

2. Intervertebral disk prosthesis according to claim 1, characterised in that the lower plate (2) comprises male means cooperating with female means of the core (3).

3. Intervertebral disk prosthesis according to claim 1, characterised in that the lower plate (2) comprises female means cooperating with male means of the core (3).

4. Intervertebral disk prosthesis according to any one of claims 1 to 3, characterised in that the angle is obtained in that the core (3) forms an acute angle in the front-rear direction (F).

5. Intervertebral disk prosthesis according to claim 4, characterised in that the same plates (1, 2) can be assembled with cores (3) of different thicknesses.

6. Intervertebral disk prosthesis according to any one of claims 4 or 5, characterised in that the angle between the upper (1) and lower (2) plates is between 0° and 15°.

5 7. Intervertebral disk prosthesis according to any one of claims 1 to 6, characterised in that the core (3) is movable with respect to the upper (1) and/or lower (2) plates, which makes it possible to compensate for positioning defects of the three parts (1, 2, 3) of the prosthesis with respect to each other.

10 8. Intervertebral disk prosthesis according to any one of claims 1 to 7, characterised in that at least part (10) of the lower surface of the upper plate (1) is concave and complementary to the upper surface (31) of the core (3).

15 9. Intervertebral disk prosthesis according to any one of claims 1 to 8, characterised in that the dimensions of each male means are slightly less than those of each female means so as to enable a slight clearance between the core (3) and the lower plate (2).

20 10. Intervertebral disk prosthesis according to any one of claims 1 to 8, characterised in that the dimensions of each male means are substantially the same as those of each female means so as to prevent any clearance between the core (3) and the lower plate (2).

25 11. Intervertebral disk prosthesis according to any one of claims 2 and 4 to 10, characterised in that the male means of the lower plate (2) are two pins (20) curved towards the inside of the prosthesis and located opposite each other on two edges (21, 22) of the prosthesis, and in that the female means of the core (3) are two recesses (30).

12. Intervertebral disk prosthesis according to claim 11, characterised in that at least one of the pins (20) is replaced by a lug equipped with a drilling (200) whereon a tag (23) using a dowel (24) entering the drilling (200).

30 13. Intervertebral disk prosthesis according to any one of claims 2 and 4 to 10, characterised in that the male means of the lower plate (2) are two

dowel pins (25) located in the vicinity of the centre of the lower plate (2), and in that the female means of the core (3) are two wells (35).

14. Intervertebral disk prosthesis according to any one of claims 2 and 4 to 10, characterised in that the male means of the lower plate (2) are two walls located opposite each other in the vicinity of two edges (21, 22) of the prosthesis, and in that the female means of the core (3) are recesses.

15. Intervertebral disk prosthesis according to any one of claims 2 and 4 to 10, characterised in that the male means of the lower plate (2) are a rib located at the centre of the prosthesis, and in that the female means of the core (3) are a groove.

16. Intervertebral disk prosthesis according to any one of claims 1 to 15, characterised in that the core (3) is made of polyethylene.

17. Intervertebral disk prosthesis according to any one of claims 1 to 16, characterised in that the lower plate (2) comprises one or more openings (28, 29) in the vicinity of its front side, provided to receive prosthesis anchoring means (4, 5) in a vertebra.

18. Intervertebral disk prosthesis according to claim 17, characterised in that the opening (28) of the lower plate (2) is rectangular, and in that the anchoring means (4) consist of a body (40), forming an acute angle with the lower plate (2), and a head (41).

19. Intervertebral disk prosthesis according to claim 17, characterised in that the openings (29) of the lower plate (2) are circular, and in that the anchoring means (5) are nail-shaped.

20. Intervertebral disk prosthesis according to any one of claims 1 to 19, characterised in that the upper plate (1) is convex on at least part of its upper surface to fit into the shape of the vertebrae.

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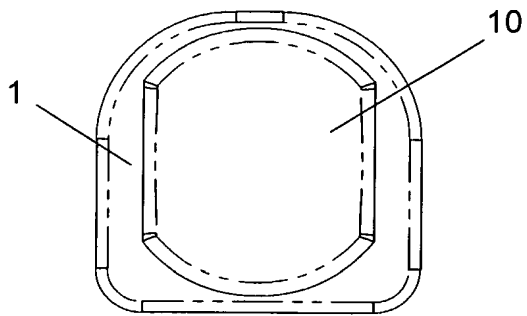


Figure 1a

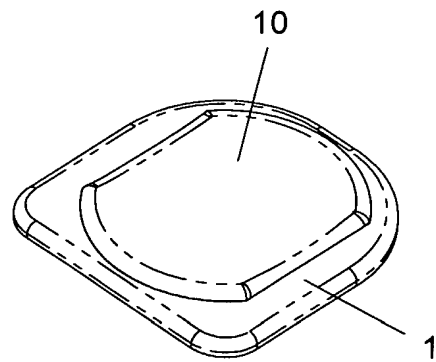


Figure 1b

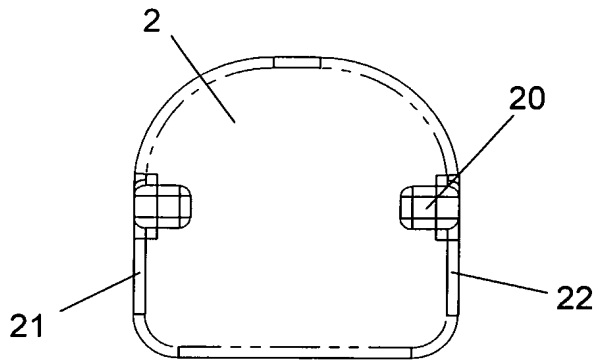


Figure 2a

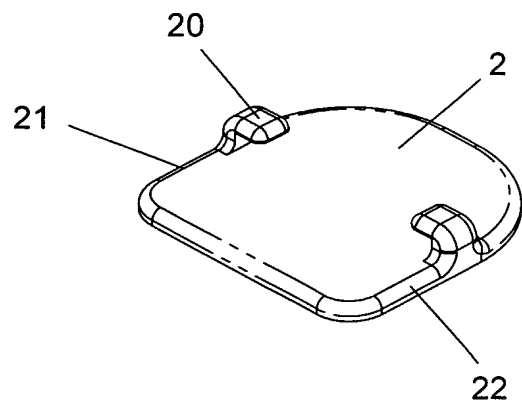


Figure 2b

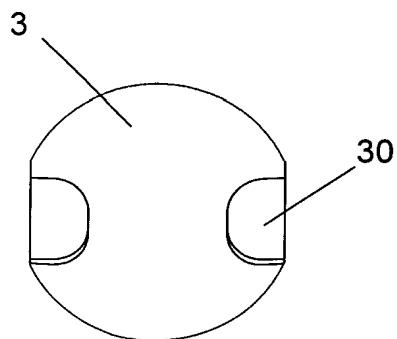


Figure 3a

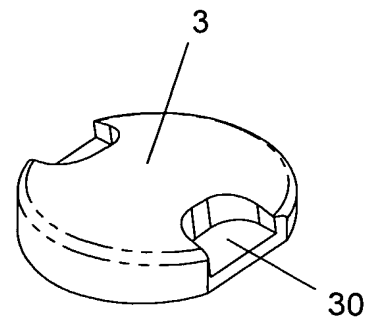


Figure 3b

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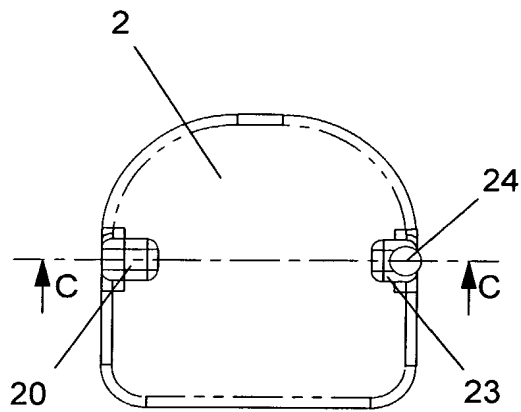


Figure 9a

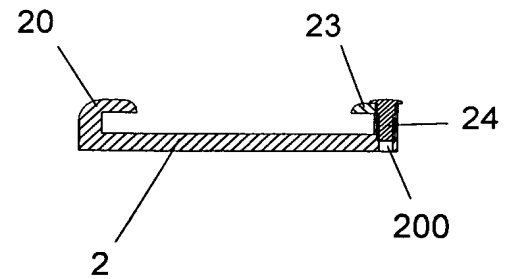


Figure 9b

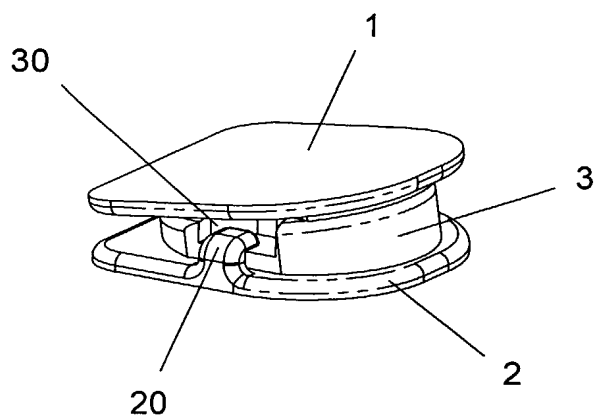


Figure 4a

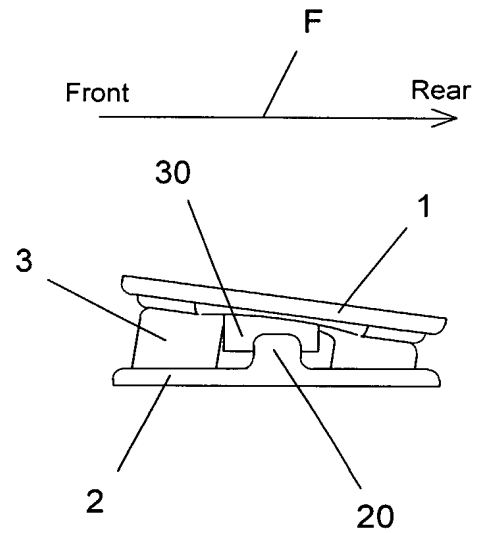


Figure 4b

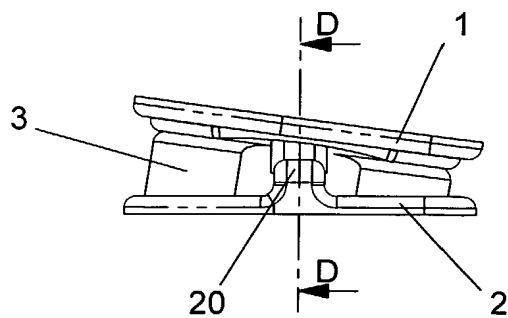


Figure 5a

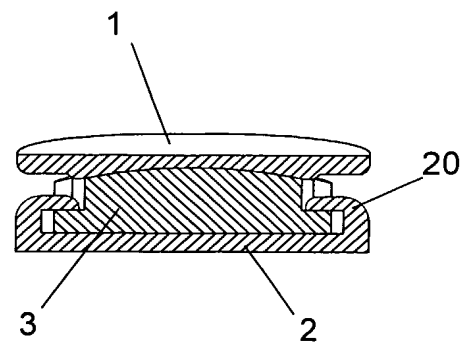


Figure 5b

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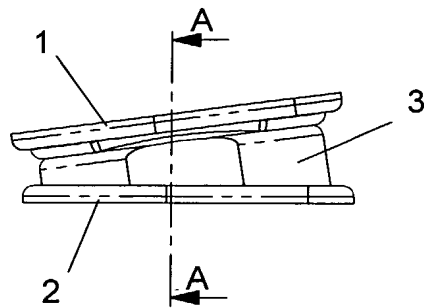


Figure 6a

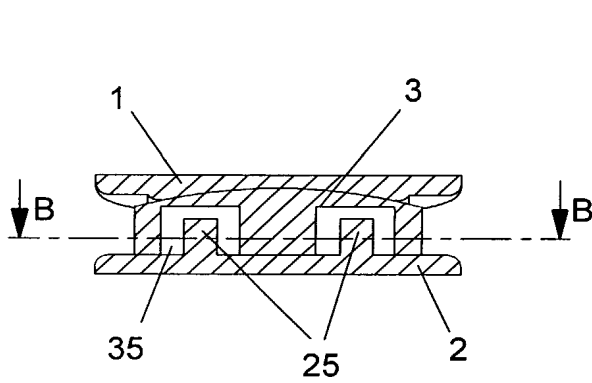


Figure 6b

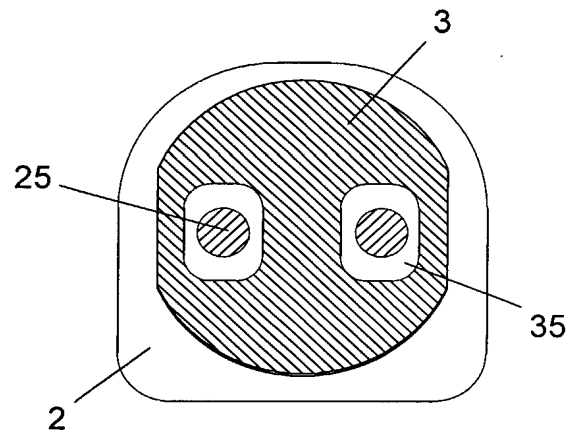


Figure 6c

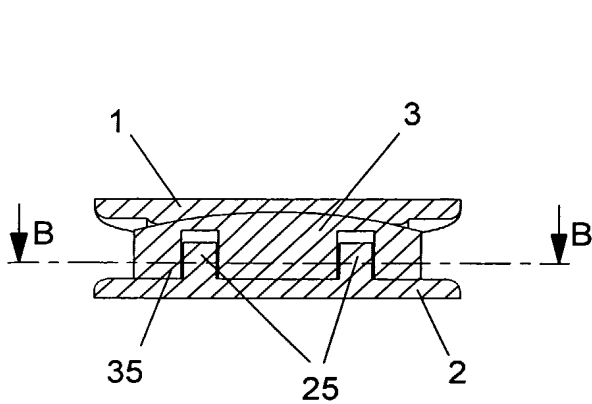


Figure 6d

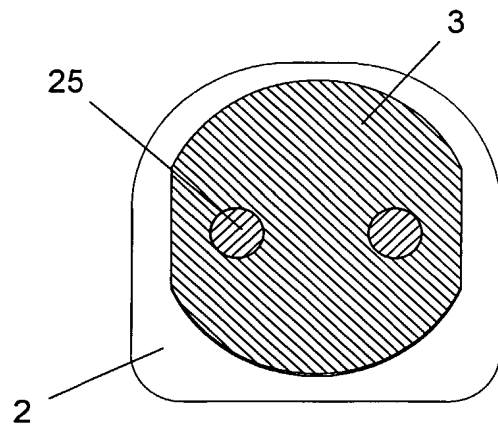


Figure 6e

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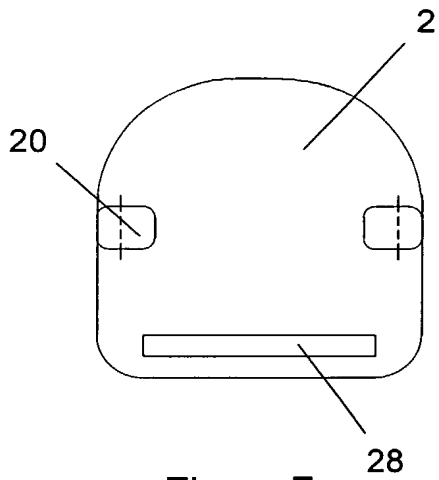


Figure 7a

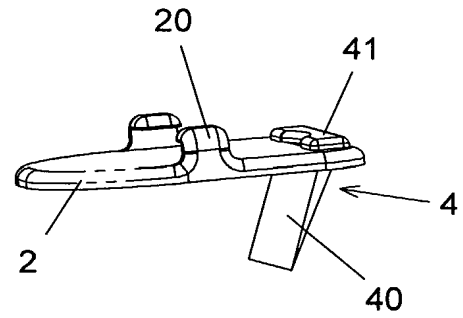


Figure 7b

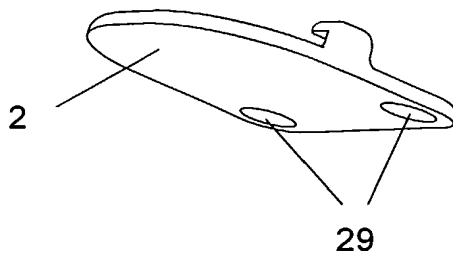


Figure 8a

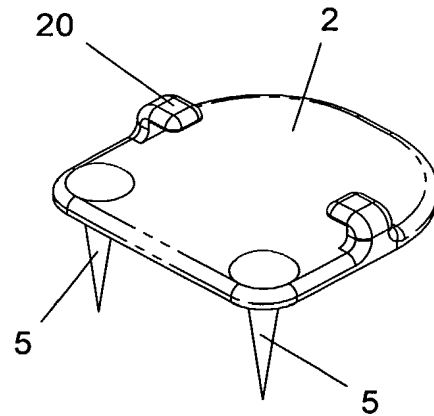


Figure 8b

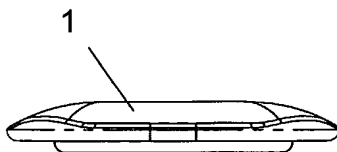


Figure 10a

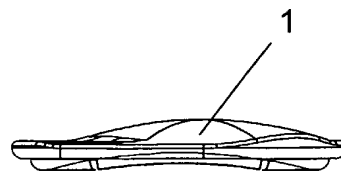


Figure 10b

INTERNATIONAL SEARCH REPORT

International Application No
PCT/15 03/04872

A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 368 350 B1 (GRIFFITH STEVEN L ET AL) 9 April 2002 (2002-04-09) figures 20-33 column 8, line 36 -column 10, line 6	1-3, 7-10, 14-17,19
A	---	4-6
X	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) claims 1,9-7; figures page 12, paragraphs 1,3 --- -/--	1-3,7,8, 10,11, 14-16

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

24 February 2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04872

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 560 141 A (LINK WALDEMAR GMBH CO) 15 September 1993 (1993-09-15) figures 8-15 column 3, line 48 - line 50 column 4, line 57 -column 5, line 43 -----	1-3, 7-10, 15-17,19
X	WO 00 74606 A (SDGI HOLDINGS INC ;ZDEBLICK THOMAS A (US); MCKAY WILLIAM F (US)) 14 December 2000 (2000-12-14) claim 1; figures 1-7,28,35,38,49A,49B page 16, line 25 - line 29 page 17, line 16 - line 30 page 22, line 22 -page 23, line 8 page 23, line 30 -page 24, line 1	1,2, 4-10,14, 20
A	-----	11

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04872

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6368350	B1	09-04-2002	AU 3873000 A WO 0053127 A1	28-09-2000 14-09-2000
WO 0101893	A	11-01-2001	DE 29911422 U1 WO 0101893 A1 AU 7224500 A BR 9917397 A CA 2391330 A1 EP 1194088 A1 JP 2003503154 T	12-08-1999 11-01-2001 22-01-2001 05-03-2002 11-01-2001 10-04-2002 28-01-2003
EP 0560141	A	15-09-1993	DE 4208116 A1 AT 144695 T DE 59304327 D1 EP 0560141 A1 ES 2094393 T3 JP 3017371 B2 JP 6007391 A US 5401269 A	23-09-1993 15-11-1996 05-12-1996 15-09-1993 16-01-1997 06-03-2000 18-01-1994 28-03-1995
WO 0074606	A	14-12-2000	AU 5320100 A CA 2376097 A1 EP 1185221 A1 JP 2003501142 T WO 0074606 A1 US 2002082701 A1 US 6402785 B1	28-12-2000 14-12-2000 13-03-2002 14-01-2003 14-12-2000 27-06-2002 11-06-2002

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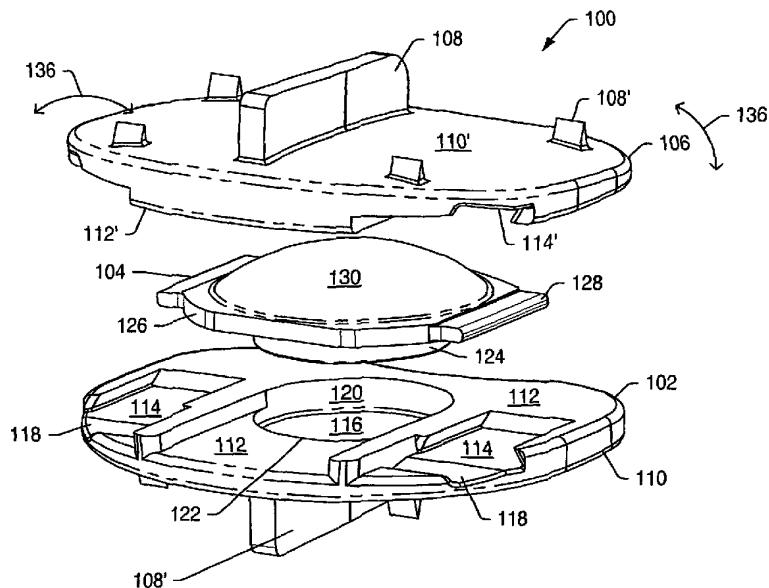
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(74) Agent: **MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.**; MEYERTONS, Eric B., P.O. Box 398, Austin, TX 78767-0398 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MOVABLE DISC IMPLANT



(57) **Abstract:** A disc implant is provided which maintains intervertebral spacing and stability within the spine. In an embodiment, a disc implant may include three or more components. Components of the implant may imitate certain physiological movements associated with a healthy spine. In certain embodiments, the components of the implant may limit physiological movements to within certain ranges, imitating normal spinal movements.

WO 2004/041131 A2

TITLE: MOVABLE DISC IMPLANT**BACKGROUND****1. Field of Invention**

The present invention generally relates to the field of medical devices. Some embodiments of the invention relate to spinal disc implants and instruments used to insert the implants. Other embodiments of the invention relate to methods of forming spinal disc implants and methods for positioning the implants during surgical procedures.

2. Description of Related Art

Bone may be subject to degeneration caused by trauma, disease and/or aging. Degeneration may destabilize bone and affect surrounding structures. For example, destabilization of a spine may result in alteration of a natural spacing between adjacent vertebrae. Alteration of a natural spacing between adjacent vertebrae may subject nerves that pass between vertebral bodies to pressure. Pressure applied to the nerves may cause pain and/or nerve damage. Maintaining the natural spacing between vertebrae may reduce pressure applied to nerves that pass between vertebral bodies. A disc implant may be used to maintain the natural spacing between vertebrae and to inhibit relative motion of the vertebrae.

A disc space may be created by full or partial removal of an intervertebral disc between two vertebral bodies. Spinal implants for a lumbar region of the spine may be positioned in an intervertebral space after a discectomy procedure. The implant may be inserted using an anterior, lateral and/or posterior approach. The spinal implant may be a fusion device or an artificial disc. Conventional systems and methods for posterolateral spinal fusion may involve dissecting and retracting soft tissue proximate the surgical site. Dissection and retraction of soft tissue may cause trauma to the soft tissue and extend recovery time. Minimally invasive procedures and systems may reduce recovery time as well as trauma to the soft tissue surrounding a stabilization site.

Spinal disc implants and/or disc implant insertion instruments are described in U.S. Patent No. 5,676,701 to Yuan et al.; U.S. Patent No. 5,401,269 to Buttner-Janz et al.; U.S. Patent No. 5,370,697 to Baumgartner; U.S. Patent No. 5,314,477 to Marnay and International Application No. WO 01/19295 to Marnay.

SUMMARY

In certain embodiments, a disc implant may be used to stabilize vertebrae of a human spine while allowing normal movement of the vertebrae relative to each other. An artificial disc implant may replace a diseased or defective intervertebral disc. An artificial disc implant may be easy to install with only minimal intrusion to adjacent tissue and muscle. A disc implant may introduce minimal risk of dural damage or neural damage during installation and use.

An artificial disc implant may include one or more engaging plates and one or more members. Engaging plates may fit between and engage adjacent vertebrae of the spine. The plates may maintain a space between the adjacent vertebrae. One or more members may be positioned in the space between the engaging plates. Engaging plates and members may be designed to allow axial rotation, anteroposterior movement and/or lateral movement of adjacent vertebrae (i.e., the spine). Lateral movement may include lateral bending. Anteroposterior movement may include flexion and/or extension. In some embodiments, a range of motion of one engaging plate relative to another engaging plate may be limited.

In some embodiments, an engaging plate may include a recess complementary to a portion of a member. In certain embodiments, an engaging plate may include slots. The slots may be dovetailed. The slots may be complementary to a portion of an instrument used to insert engaging plates between vertebrae. In some embodiments, slots may be formed at an angle relative to an anterior-posterior axis of an engaging plate. In some embodiments, an angular orientation of a recess may correspond to an angle of slots in an engaging plate. Angulation of the slots may allow insertion of a disc implant using a modified (e.g., angulated) anterior approach. A modified anterior approach may facilitate retraction of blood vessels above the L5 vertebrae.

In certain embodiments, an engaging plate may include one or more coupling projections. One or more coupling projections may penetrate a vertebral surface. In some embodiments, a coupling projection may be positioned in a recess formed in a vertebral surface. Once positioned in the vertebra, the coupling projection may inhibit movement of an engaging plate relative to the vertebra.

In some embodiments, a disc implant may include two engaging plates and a member. The member may have a convex portion. The engaging plates may be shaped to complement surfaces of the member, including the convex portion. The member may be positioned between the engaging plates to allow axial rotation, lateral and/or anteroposterior movement of a first engaging plate relative to a second engaging plate.

In disc implant embodiments including two engaging plates and a member, the member may allow the engaging plates to undergo three independent components of motion relative to each other. The member may have a convex portion and a recess. The recess of the member may complement a projection on a first engaging plate to allow rotation of a first engaging plate relative to the member. The convex portion of the member may complement a concave portion of the second engaging plate to allow anteroposterior and/or lateral movement of the second engaging plate relative to the member.

In some embodiments, a disc implant may include two engaging plates and two members. The members may allow the engaging plates to undergo three independent components of motion relative to each other. A convex portion of a first engaging plate may complement a concave portion of a first member to allow lateral bending of the first engaging plate relative to a second engaging plate. A projection on the first member may complement a recess in a second member to allow axial rotation of the first engaging plate relative to the second engaging plate. A convex portion of the second member may complement a concave portion of the second engaging plate to allow movement of the engaging plates relative to each other.

In other disc implant embodiments including two engaging plates and two members, a first member may couple to a first engaging plate to allow axial rotation of the first engaging plate relative to a second engaging plate. A convex portion of the first member may complement a concave portion of a second member to allow lateral bending of the engaging plates relative to each other. A convex portion of the second member may complement a concave portion of the second engaging plate to allow flexion and/or extension of vertebrae adjacent to the engaging plates.

In disc implant embodiments including a member and two engaging plates, a member may have a spherical shape. The member may be positioned between concave portions of the engaging plates. The member may allow axial rotation, anteroposterior movement and/or lateral movement of the engaging plates relative to each other.

An instrumentation set for a disc implant insertion procedure may include various guidance and/or insertion instruments. Insertion instruments may include, but are not limited to, chisels, reamers, hex drivers, slap hammers, inserters, distractors and pushers. An instrumentation set may include trial endplates and disc implant components. Trial endplates may be plates of various sizes and lordotic alignment. Trial endplates may include stops and/or instrument guides to facilitate removal of bone material from a vertebral surface. Distractors in combination with trial endplates

may determine a size, height and lordotic alignment of implant components to be used in a disc implant insertion procedure. Implant components may include, but are not limited to, engaging plates of various sizes and lordotic alignment and members of various sizes and shapes.

An inserter may be used to position engaging plates between two vertebrae. A distractor may be positioned between the engaging plates to establish a desired separation distance between the engaging plates. One or more members may be guided through a body of the distractor and into the space between the engaging plates. In some embodiments, members may be guided through a body of a distractor with a pusher. The pusher may maintain the position of the members when a distractor is removed from the inserter.

In certain embodiments, trial endplates, members and engaging plates may be formed from various materials including plastics, ceramics, polymers, composites and metals. Materials may be chosen based on factors including, but not limited to, durability, biocompatibility, galling characteristics, mechanical strength and/or wear properties. In some embodiments, radiological markers may be used in combination with materials that are "invisible" to radiological techniques. In certain embodiments, steps may be taken to adjust a coefficient of friction of materials chosen to form members (e.g., surfaces may be polished or roughened). In other embodiments, surfaces of engaging plates and/or members may be coated to reduce noise created by contact of a member with an engaging plate and/or another member.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the present invention will become apparent to those skilled in the art with the benefit of the following detailed description and upon reference to the accompanying drawings in which:

FIG. 1 is a perspective view of components of a disc implant.

FIG. 2 is a bottom view of an embodiment of an engaging plate.

FIG. 3 is a bottom view of an embodiment of an engaging plate.

FIG. 4 is a cross-sectional view of an embodiment of a disc implant.

FIG. 5 is a side view of components of a disc implant.

FIG. 6 is a perspective view of components of a disc implant.

FIG. 7 is a cross-sectional view of an embodiment of a disc implant.

FIG. 8 is a bottom view of an engaging plate.

FIG. 9 is a perspective view of components of a disc implant.

FIG. 10 is a cross-sectional view of an embodiment of a disc implant.

FIG. 11 is a perspective view of components of a disc implant.

FIG. 12 is a top view of a member.

FIG. 13 is a cross-sectional view of an embodiment of a disc implant.

FIG. 14 is a perspective view of components of a disc implant.

FIG. 15 is a cross-sectional view of an embodiment of a disc implant.

FIG. 16 is a perspective view of components of a disc implant.

FIG. 17 is a cross-sectional view of an embodiment of a disc implant.

FIG. 18 is a perspective view of components of a disc implant.

FIG. 19 is a cross-sectional view of an embodiment of a disc implant.

FIG. 20 is a side view of an embodiment of a disc implant.

FIG. 21 is a perspective view of an embodiment of a disc implant.

FIG. 22 is a cross-sectional view of an embodiment of a disc implant.

FIGS. 23-27 depict embodiments of coupling projections.

FIG. 28 is a perspective view of an embodiment of an inserter.

FIG. 29 is a side view of a portion of an embodiment of an inserter coupled to engaging plates.

FIG. 30 is a side view of an embodiment of an inserter.

FIG. 31 is a perspective view of an embodiment of a slap hammer coupled to an inserter.

FIG. 32 is a perspective view of an embodiment of a distractor.

FIG. 33 is a perspective view of an embodiment of a distractor positioned in an inserter.

FIG. 34 is a perspective view of an embodiment of a pusher.

FIG. 35 is a side view of an embodiment of a pusher coupled to an inserter.

FIG. 36 is a perspective view of an embodiment of an instrument guide.

FIG. 37 is a perspective view of an instrument guide coupled to an inserter.

FIG. 38 and FIG. 38A depict an embodiment of a chisel.

FIG. 39 is a perspective view of a chisel in working relation to an instrument guide.

FIG. 40 is a perspective view of a reamer in working relation to an instrument guide.

FIG. 41 depicts embodiments of trial spacers.

FIG. 42 is a bottom view of an embodiment of a trial endplate.

FIG. 43 is a perspective view of a member seater.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. The drawings may not be to scale. It should be understood that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION

An intervertebral disc implant may be used to stabilize a portion of the spine. The artificial intervertebral disc implant may replace all or a portion of an intervertebral disc that requires replacement due to degeneration from natural wear, trauma or disease. The artificial intervertebral disc may restore the normal separation distance between the vertebrae and allow normal movement and flexibility of the spine.

Disc implants may allow movement of adjacent vertebrae relative to each other in ranges associated with normal limits for human vertebrae. Disc implants may allow axial rotation, axial compression and lateral and/or anteroposterior movement. In a human spine, axial rotation may include rotation of about 0.1° to about 3° about a longitudinal axis of the spine. An axis of rotation between vertebrae may be off-center due to the fibrocartilaginous nature of an intervertebral disc. An axis of rotation between two vertebrae may be located posterior to a mid-point between the vertebrae. Lateral movement may include lateral bending. Lateral bending may include motion to the left and/or right up to a maximum of about 0.5° to about 10° . Anteroposterior movement may include flexion and/or extension. Flexion may include anterior motion up to a maximum of about 0.5° to about 20° . Extension may include posterior motion up to a maximum of about 0.5° to about 10° .

Some implant embodiments may inhibit movement outside of normal limits for vertebrae. Limiting a range of motion may decrease chances of injury. Tissue and structure adjacent to vertebrae separated by a disc may limit some ranges of motion. For example, surrounding tissue and structure may limit axial rotation of vertebrae.

In some embodiments, artificial disc implants may be used to replace a disc or discs in the lumbar region of a spine. In certain embodiments, artificial disc implants may be used in cervical or thoracic portions of the spine. In some embodiments, artificial disc implants may be used with other systems or devices to provide stability to the spine. In other embodiments, a disc implant may be used as a stand-alone system.

FIG. 1 is a perspective view of components of an embodiment of a disc implant that may be inserted between two vertebrae. Disc implant 100 may include engaging plate 102, member 104 and engaging plate 106. When the implant is installed in a patient, each engaging plate of the implant may cover at least 70% of the vertebral surface that the engaging plate contacts. Member 104 may separate engaging plate 102 from engaging plate 106. In certain embodiments, member 104 may be held between engaging plates 102, 106 at least partially by pressure resulting from natural compression of the spine.

Engaging plates 102, 106 may contact adjacent vertebrae to anchor the disc implant to the spine. Coupling projections 108 positioned on outer surfaces 110, 110' of engaging plates 102, 106 may be positioned in a recess of a vertebral surface. Coupling projections 108' positioned on outer surfaces 110, 110' of engaging plates 102, 106 may penetrate into vertebral surfaces to inhibit movement of the engaging plates relative to the vertebrae. In certain embodiments, engaging plates may be coupled to vertebrae using methods other than, or in addition to, coupling projections 108, 108'. For example, fasteners may be used to attach an engaging plate to a vertebra. Fasteners may include, but are not limited to, screws, nails, rivets, trocars, pins and barbs.

Inner surface 112 of engaging plate 102 may include slots 114 and recess 116. Slots 114 may have a cross-sectional shape including, but not limited to, square, rectangular, trapezoidal, or irregular. Inner surface 112' of engaging plate 106 may include slots 114' that align with slots 114 of engaging plate 102 when disc implant 100 is assembled. Slots 114, 114' may include indents 118. Indents 118 may engage an instrument used to facilitate insertion of implant 100 during a surgical procedure. In some embodiments, slots 114, 114' may be dovetailed. Slots 114, 114' may allow use of insertion instruments without adding a height and/or a thickness to the overall dimension of implant 100.

In some embodiments, slots in an engaging plate may be parallel or substantially parallel to an anterior-posterior axis of the engaging plates. FIG. 2 depicts an embodiment of engaging plate 106 wherein slots 114' are parallel to anterior-posterior axis 119. In some embodiments, slots may be at acute angle relative to the anterior-posterior axis of the engaging plate. FIG. 3 depicts an embodiment of engaging plate 106 wherein slots 114' are angled relative to anterior-posterior axis 119. Slots 114, 114' may be formed at an angle ranging from about 15° to about 30° relative to anterior-posterior axis 119. In some embodiments, slots 114, 114' may be formed at about a 25° angle relative to anterior-posterior axis 119. Angulation of slots 114, 114' may allow insertion of implant 100 using a modified (e.g., angulated) anterior approach. In some embodiments, an angular orientation of recess 116 may correspond to angulation of slots 114, 114'. A modified anterior approach may facilitate retraction of blood vessels above the L5 vertebrae. In some embodiments, engaging plates 102, 106 with slots 114, 114' angled relative to anterior-posterior axis 119 may not include a central coupling projection (i.e., a keel).

Recess 116 of engaging plate 102 may have a cross-sectional shape including, but not limited to, circular, elliptical, square, rectangular or irregular. Sides of recess 116 may be tapered. Posterior side 120 of recess 116 may be at least twice the height of anterior side 122 of recess 116. A height difference between anterior side 122 and posterior side 120 may minimize overdistraction of the vertebrae required during positioning of member 104 between engaging plates 102, 106 in a disc implant procedure. In some embodiments, a bottom portion of the recess may include an opening or openings to allow residual body fluids and/or bone matter to be removed from the recess.

Base 124 of member 104 may fit in recess 116 of engaging plate 102. Base 124 may substantially conform to the shape of recess 116. In some embodiments, member 104 may be a tapered boss. A width of base 124 that fits in recess 116 may be slightly less than a width of the recess to allow member 104 to translate in the recess. Recess 116 may maintain a position of member 104 between engaging plates 102, 106.

Member 104 may include center section 126. A height of center section 126 of member 104 may add thickness to a height of implant 100. Center section 126 may range in height from about 5 mm to about 20 mm. In certain embodiments, center section 126 may have a height of about 9 mm. In some embodiments, center section 126 may have a height of about 11 mm. In other embodiments, center section 126 may have a height of about 13 mm.

Center section 126 may include projections 128. Projections 128 may be an integral part of center section 126. In some embodiments, projections 128 may be glued, press fit and/or welded to center section 126. Projections 128 may be the same height as center section 126. Projections 128 may engage an instrument to facilitate insertion of member 104 between engaging plates 102, 106.

Member 104 may include convex portion 130. Convex portion 130 may be, but is not limited to being, an ellipsoidal section, an ovate section or a spherical section. Inner surface 112' of engaging plate 106 may include a recess. FIG. 2 depicts a bottom view of inner surface 112' of engaging plate 106 shown in FIG. 1. Recess 132 may complement convex portion 130 of member 104. In some embodiments, a height of convex portion 130 may exceed a depth of recess 132. As used herein, "complement" or "complementary" refers to shapes of implant components that fit together to allow smooth relative motion of the components.

Fig. 3 depicts a bottom view of inner surface 112' of an embodiment of engaging plate 106 with slots 114' angled relative to anterior-posterior axis 119. Slots 114' may be formed at an angle ranging from about 15° to about 30° relative to anterior-posterior axis 119. In some embodiments, slots 114' may be formed at about a 25° angle relative to anterior-posterior axis 119. In certain embodiments, an orientation of recess 132 may be angled to correspond to an angle of slots 114'. Angulation of slots 114' may allow insertion of implant 100 using a modified (e.g., angulated) anterior approach.

FIG. 4 depicts a cross-sectional view of the implant shown in FIG. 1 after the implant has been assembled. Convex portion 130 of member 104 may complement recess 132 of engaging plate 106. A shape of convex portion 130 may allow engaging plate 106 to move (e.g., rock) in an anteroposterior plane and/or a mediolateral plane relative to engaging plate 102. Movement of engaging plate 106 relative to engaging plate 102 in the anteroposterior plane indicated by arrow 134 may allow flexion and extension of vertebrae adjacent to the engaging plates. Movement of engaging plate 106 relative to engaging plate 102 in the mediolateral plane indicated by arrow 136 in FIG. 1 may allow lateral bending of the vertebrae adjacent to engaging plates 102, 106. Engaging plate 106 may rotate relative to engaging plate 102 around axis of rotation 138 in the plane indicated by arrow 140. In some embodiments, axial rotation of engaging plate 106 relative to engaging plate 102 may be limited by tissue, bone or other material in the patient.

In some embodiments, a height of convex portion 130 and a depth of recess 132 may be chosen to limit lateral movement of engaging plate 106 relative to engaging plate 102. For example, a height of convex portion 130 may allow engaging plate 106 to contact engaging plate 102 when engaging plate 106 rocks in the direction of engaging plate 102. Contact of inner surfaces 112, 112' of engaging plates 102, 106 may provide a limit to anteroposterior movement of engaging plate 106 relative to engaging plate 102. Contact of inner surfaces 112, 112' of engaging plates 102, 106 may limit flexion and/or extension of the adjacent vertebrae. A height of convex portion 130 may determine maximum flexion and/or extension allowed by the implant. In some embodiments, a maximum amount of flexion may be limited to a range between about 0.5° and about 20°. In some embodiments, maximum flexion allowed by the implant may be

about 10°. In other embodiments, maximum flexion allowed by the implant may be about 15°. In some embodiments, a maximum amount of extension may be limited to a range between about 0.5° and about 12°. In some embodiments, maximum extension allowed by the implant may be about 8°. In other embodiments, maximum extension allowed by the implant may be about 5°.

In some embodiments, components of an implant may include surfaces that contact to limit a maximum amount of lateral bending. In some embodiments, an implant may allow equal amounts of lateral bending so that the patient can laterally bend the same amount to the right or the left. In some embodiments, a maximum amount of lateral bending to the left may be different than a maximum amount of lateral bending to the right to accommodate specific needs of a patient. In some embodiments, an implant may be designed to allow a maximum amount of lateral bending within a range between $\pm 0.5^\circ$ to about $\pm 15^\circ$. In some embodiments, the maximum amount of lateral bending may be about $\pm 10^\circ$. In some embodiments, the maximum amount of lateral bending allowable by an implant may be about $\pm 5^\circ$.

In alternative embodiments, a concave portion of a member may complement a convex portion of an engaging plate. As shown in FIG. 5, convex portion 142 of engaging plate 106 may complement recess 144 of member 104 to form an implant. A large contact area between engaging plate 106 and member 104 may advantageously distribute a compressive load applied to the implant over a relatively large area.

FIG. 6 depicts a perspective view of components of an implant embodiment. Implant 100 may allow a full range of physiological movement of vertebrae adjacent to the implant. Inner surface 112 of engaging plate 102 may include at least one projection. Projection 146 may be coupled to engaging plate 102. In some embodiments, projection 146 may be an integral part of engaging plate 102. Projection 146 may have a shape that allows engaging plate 102 to rotate freely relative to member 104. The shape of projection 146 may be, but is not limited to being, tapered, round or square. Member 104 may include recess 148 (shown in FIG. 7). Recess 148 may complement projection 146. Recess 148 may have a slightly larger cross section than projection 146 to allow engaging plate 102 to move relative to member 104. A size and/or shape of recess 148 relative to projection 146 may determine a range of rotation of member 104 relative to engaging plate 102.

As depicted in FIG. 7, recess 148 and projection 146 may define axis of rotation 138. Friction between engaging plate 102 and member 104 may be low enough to allow rotation of the engaging plate relative to the member. Engaging plate 102 may rotate relative to member 104 as indicated by arrow 140. Rotation of engaging plate 102 relative to member 104 may imitate axial rotation of the spine. A large contact area between recess 148 of member 104 and projection 146 of engaging plate 102 may distribute a compressive load applied to implant 100 over a relatively large surface area.

Member 104 may include convex portion 150. Inner surface 112' of engaging plate 106 may include recess 152. Recess 152 of engaging plate 106 may complement convex portion 150 of member 104. The shape of convex portion 150 may allow engaging plate 106 to move (e.g., rock) relative to member 104. Movement of engaging plate 106 relative to member 104 may allow lateral movement (e.g., lateral bending) of vertebrae adjacent to the engaging plates. In an alternative embodiment, member 104 may include a recess complementary to a convex part of engaging plate 106.

Convex portion 150 may have an arcuate cross-sectional shape in an anteroposterior plane and/or in a mediolateral plane. An arcuate shape of convex portion 150 in the anteroposterior plane may allow engaging plate 106 to rock relative to engaging plate 102 in the directions indicated by arrows 134 in FIG. 7. Movement of engaging plate 106 relative to engaging plate 102 in the anteroposterior plane may allow flexion and extension of vertebrae adjacent to the engaging plates. An arcuate shape of convex portion 150 in the mediolateral plane may allow engaging plate 106 to move relative to engaging plate 102 in directions indicated by arrow 136 in FIG. 6. Movement of engaging plate 106

relative to engaging plate 102 in the mediolateral plane may allow lateral bending of vertebrae adjacent to the engaging plates.

FIG. 8 depicts a bottom view of inner surface 112' of engaging plate 106 shown in FIG. 7. Engaging plate 106 may include recess 152. A shape of recess 152 may complement convex portion 150 of member 104. Recess 152 may be concave with an arcuate cross-sectional shape in an anteroposterior plane and/or in a mediolateral plane. A shape of recess 152 may allow movement of engaging plate 106 relative to member 104 in an anteroposterior plane and/or in a mediolateral plane. Movement of engaging plate 106 relative to member 104 in an anteroposterior plane and/or in a mediolateral plane may allow flexion, extension and/or lateral bending of vertebrae adjacent to engaging plates 102, 106.

In some embodiments, engaging plate 106 may include limiter 154, as shown in FIG. 7. Limiter 154 may be positioned to contact surface 156 of member 104. Contact of limiter 154 and surface 156 may limit posterior movement of engaging plate 106 relative to engaging plate 102. Contact of limiter 154 and surface 156 may therefore limit extension of vertebrae adjacent to engaging plates 102, 106. A height of limiter 154 relative to inner surface 112' of engaging plate 106 and/or a height of surface 156 relative to inner surface 112 of engaging plate 102 may be chosen to limit extension of vertebrae adjacent the implant. Maximum extension allowed by implant 100 may range from about 3° to about 12°. In some embodiments, maximum extension allowed by implant 100 may be about 8°. In other embodiments, maximum extension allowed by implant 100 may be about 5°.

In some embodiments, inner surface 112' of engaging plate 106 may contact surface 156 of member 104. Contact of inner surface 112' with surface 156 may limit anterior movement of engaging plate 106 relative to engaging plate 102. Contact of inner surface 112' of engaging plate 106 with surface 156 of member 104 may limit flexion of vertebrae adjacent engaging plates 102, 106. A height of surface 156 relative to inner surface 112 of engaging plate 102 may be chosen to limit flexion of vertebrae adjacent to engaging plates 102, 106. Maximum flexion allowed by implant 100 may range from about 5° to about 20°. In some embodiments, maximum flexion allowed by implant 100 may be about 10°. In other embodiments, maximum flexion allowed by implant 100 may be about 15°.

FIG. 9 depicts a perspective view of components of an embodiment of an implant. Implant 100 may allow limited axial rotation of vertebrae adjacent to engaging plates 102, 106. Engaging plate 102 may include recess 158. Edges of recess 158 may be arced. The arcs may share a common center point. Base 124 of member 104 may fit in recess 158. A surface of base 124 may substantially conform to an arced surface of recess 158. A width of base 124 may be less than a width of recess 158 such that member 104 may be able to translate in recess 158 along curves defined by the edges of the recess.

FIG. 10 depicts a cross-sectional view of the implant shown in FIG. 9 after the implant has been assembled. Base 124 of member 104 may complement recess 158 of engaging plate 102. Axis of rotation 138 may be at or near the centroid of engaging plates 102, 106 or offset from the engaging plates. Rotation of engaging plate 102 relative to engaging plate 106 may allow rotation of vertebrae adjacent implant 100.

A shape of recess 158 may allow engaging plate 102 to rotate axially relative to engaging plate 106 in the plane indicated by arrow 140. Movement of base 124 in recess 158 may limit axial rotation of the vertebrae adjacent to engaging plates 102, 106. Maximum axial rotation allowed by implant 100 may range from about $\pm 0.1^\circ$ to about $\pm 6^\circ$. In some embodiments, maximum axial rotation allowed by implant 100 may be about $\pm 3^\circ$. In other embodiments, maximum axial rotation allowed by implant 100 may be about $\pm 1^\circ$.

Engaging plate 106 may include recess 152. Recess 152 may complement convex portion 150 of member 104. In an alternative embodiment, member 104 may include a recess complementary to a convex portion of engaging plate 106. Convex portion 150 may have an arcuate cross-sectional shape in an anteroposterior plane and/or in a mediolateral

plane. An arcuate shape of convex portion 150 in an anteroposterior plane may allow engaging plate 106 to move (e.g., rock) relative to member 104 in the directions indicated by arrow 134. Movement of engaging plate 106 relative to member 104 in the anteroposterior plane may allow flexion and/or extension of the vertebrae adjacent to the engaging plates. An arcuate shape of convex portion 150 in a mediolateral plane may allow engaging plate 106 to move (e.g., rock) relative to member 104 in the directions indicated by arrows 136 in FIG. 9. Movement of engaging plate 106 relative to member 104 in the mediolateral plane may allow lateral bending of the vertebrae adjacent to the engaging plates.

In some embodiments, inner surface 112' of engaging plate 106 (shown in FIG. 10) may contact surface 156 of member 104. Contact of inner surface 112' with surface 156 may limit movement of engaging plate 106 relative to engaging plate 102 in the anteroposterior plane. Contact of inner surface 112' with surface 156 may limit flexion of the spine. In certain embodiments, a height of a surface 156 relative to inner surface 112 may be chosen to limit flexion of the spine. Maximum flexion allowed by implant 100 may range from about 5° to about 20°. In some embodiments, maximum flexion allowed by implant 100 may be about 10°. In other embodiments, maximum flexion allowed by implant 100 may be about 15°.

In some embodiments, posterior movement of engaging plate 106 relative to engaging plate 102 may be limited. Engaging plate 106 may include limiter 154. During use, limiter 154 may contact surface 156 to limit posterior movement of engaging plate 106 relative to engaging plate 102. Contact of limiter 154 with surface 156 may limit extension of the spine. A height of limiter 154 relative to inner surface 112' and/or a height of contact surface 156 relative to inner surface 112 may be chosen to limit extension of the spine. Maximum extension allowed by implant 100 may range from about 3° to about 12°. In some embodiments, maximum extension allowed by implant 100 may be about 8°. In other embodiments, maximum extension allowed by implant 100 may be about 5°.

In some embodiments, inner surface 112 of engaging plate 102 may have a convex portion. Engaging plate 102 of implant 100 shown in FIG. 11 includes convex portion 160. Convex portion 160 may have an arcuate cross-sectional shape in an anteroposterior plane and/or in a mediolateral plane. Member 104 may include recess 162, as shown in FIG. 12. Edges of recess 162 may be arced. The arcs may share a common center point. Convex portion 160 may fit in recess 162 of member 104. Convex portion 160 of engaging plate 102 may complement recess 162. A width of convex portion 160 may be less than a width of recess 162. Engaging plate 102 may translate in recess 162 along curves defined by edges of the recess.

FIG. 13 depicts a cross-sectional view of the implant shown in FIG. 11 after the implant has been assembled. Recess 162 of member 104 may complement convex portion 160 of engaging plate 102. A shape of convex portion 160 may allow relative movement of engaging plates 102, 106 in the plane indicated by arrow 140 about axis of rotation 138. Axis of rotation 138 may be at or near the centroid of implant 100 or offset from the centroid.

Maximum axial rotation allowed by implant 100 may range from about $\pm 0.1^\circ$ to about $\pm 6^\circ$. In some embodiments, maximum axial rotation allowed by implant 100 may be about $\pm 3^\circ$. In other embodiments, maximum axial rotation allowed by implant 100 may be about $\pm 1^\circ$. Rotation of engaging plate 102 relative to engaging plate 106 may be limited by a height of convex portion 160 relative to a depth of recess 162. In some embodiments, rotation of engaging plate 102 relative to engaging plate 106 may be limited by a curvature of convex portion 160 and/or a curvature of recess 162.

Inner surface 112' of engaging plate 106 may include recess 152. Recess 152 may be complementary in shape to convex portion 150 of member 104. Convex portion 150 may complement recess 152. Convex portion 150 may allow engaging plate 106 to move (e.g., rock) relative to member 104. Movement of engaging plate 106 relative to member

104 may allow lateral movement of the spine. In some embodiments, member 104 may include a recess complementary to a convex portion of engaging plate 106.

Convex portion 150 may have an arcuate cross-sectional shape in an anteroposterior plane and/or in a mediolateral plane. An arcuate shape of convex portion 150 in the anteroposterior plane may allow engaging plate 106 to move relative to member 104 in the directions indicated by arrow 134. Movement of engaging plate 106 relative to engaging plate 102 in the anteroposterior plane may allow flexion and/or extension of the spine. The arcuate shape of convex portion 150 in the mediolateral plane may allow engaging plate 106 to move relative to member 104 in the directions indicated by arrow 136 shown in FIG. 11. Movement of engaging plate 106 relative to member 104 in the mediolateral plane may allow lateral bending of the spine.

Inner surface 112' of engaging plate 106 may contact surface 156 of member 104. Contact of inner surface 112' with surface 156 may limit anterior movement of engaging plate 106 relative to engaging plate 102. Contact of inner surface 112' with surface 156 may therefore limit flexion of vertebrae adjacent to engaging plates 102, 106. A thickness of an edge of member 104 may limit flexion allowed by implant 100. Maximum flexion allowed by implant 100 may range from about 5° to about 20°. In some embodiments, maximum flexion allowed by implant 100 may be about 10°. In other embodiments, maximum flexion allowed by implant 100 may be about 15°.

In certain embodiments, disc implant 100 may include two engaging plates and two members as depicted in FIGS. 14 and 16. FIGS. 15 and 17 are cross-sectional views of implants 100 shown in FIGS. 14 and 16, respectively. Engaging plate 102 of implants 100 may have convex portion 164. Convex portion 164 may have an arcuate cross-sectional shape along at least one axis. The arcuate cross-sectional shape along one axis of convex portion 164 may increase an area of contact between engaging plate 102 and member 104. Member 104 may include recess 166. Recess 166 may complement convex portion 164. A shape of convex portion 164 may allow anteroposterior translation of member 104 relative to engaging plate 102. Translation of member 104 relative to engaging plate 102 may allow positioning of implant 100 during a spinal stabilization procedure.

A thickness of engaging plate 102 proximate convex portion 164 may exceed a thickness of engaging plate 102 proximate edges 168, 168' such that inner surfaces 112, 112'' are sloped relative to an outer surface of the engaging plate. In some embodiments, a slope of inner surface 112 may be different than a slope of inner surface 112''. In certain embodiments, a thickness of member 104 proximate recess 166 may exceed a thickness of the member at edges 170, 170' such that surfaces 172, 172' are sloped relative to surface 156.

Inner surfaces 112, 112'' and surfaces 172, 172' may be sloped to allow movement (e.g., rocking) of engaging plate 102 relative to member 104 in a mediolateral plane. Movement of member 104 in the direction indicated by arrow 136 may allow lateral bending of vertebrae adjacent to engaging plates 102, 106. Inner surfaces 112, 112'' and surfaces 172, 172' may be sloped such that lateral movement of the spine in a mediolateral plane is restricted. In some embodiments, a slope of surface 172 relative to surface 156 may be different than a slope of surface 172' relative to surface 156. In some embodiments, slopes of surfaces 172, 172' may be opposite in sign to slopes of inner surfaces 112, 112''. Movement of engaging plate 102 relative to member 104 may allow inner surfaces 112, 112'' to contact surfaces 172, 172'. Contact of inner surfaces 112, 112'' and surfaces 172, 172' may distribute a compressive load applied to implant 100 over a relatively large surface area.

Member 104 may include projection 146. Projection 146 may be coupled to member 104. In some embodiments, projection 146 may be an integral part of member 104. A shape of projection 146 may be, but is not limited to being, tapered, round or square. Member 174 may include recess 148, as depicted in FIGS. 15 and 17. Recess 148 may complement projection 146. Recess 148 may have a slightly larger cross section than projection 146 to allow

relative movement of members 104, 174. In some embodiments, member 174 may rotate relative to member 104 about axis of rotation 138 indicated by arrow 140. As shown in FIG. 15, axis of rotation 138 may be near a center of implant 100. In some embodiments, axis of rotation 138 may be located more off-center, as depicted in FIG. 17. A range of rotation of member 174 relative to member 104 may be limited by a size and/or shape of recess 148 relative to a size and/or shape of projection 146.

Surface 176 of member 174 may contact surface 156 of member 104 when projection 146 fits in recess 148. A relatively large contact area between member 104 and member 174 may distribute an effective load applied to implant 100 while allowing rotation of vertebrae adjacent to the implant. For example, projection 146 (shown in FIG. 14) has a flat surface that may increase a contact area between projection 146 and recess 148. Reducing friction between member 104 and member 174 may allow facile rotation of the members relative to each other.

Member 174 may have convex portion 178. Convex portion 178 may have an arcuate cross-sectional shape in an anteroposterior plane. Engaging plate 106 may include recess 180 (shown in FIG. 15 and FIG. 17). Recess 180 may be concave with an arcuate cross-sectional shape in an anteroposterior plane. Recess 180 may complement convex portion 178 of member 174. In some embodiments, recess 180 may have a slightly larger cross section than convex portion 178 to allow movement of engaging plate 106 relative to member 174. Movement of engaging plate 106 relative to member 174 may allow for flexion and/or extension of vertebrae adjacent to the engaging plates in the plane indicated by arrows 134 in FIGS. 15 and 17.

In some embodiments, anteroposterior and/or lateral movement of components of implant 100 relative to each other may be limited. As shown in FIGS. 14 and 15, engaging plate 106 may include limiter 154. Limiter 154 may be a projection extending from inner surface 112' of engaging plate 106. In an embodiment, limiter 154 may extend along a side of engaging plate 106. Limiter 154 may be positioned to contact surface 182 of member 174 when engaging plate 106 rocks in a posterior direction toward engaging plate 102. Increasing a length of limiter 154 may increase an area of contact between limiter 154 and member 174. Increasing the area of contact between limiter 154 and member 174 may distribute a compressive load on implant 100 over a relatively large area. Distributing the load over a relatively large area may reduce stress among components of implant 100.

Contact of limiter 154 with surface 182 may limit movement of engaging plate 106 relative to member 174. A height of limiter 154 relative to inner surface 112' and/or a distance between surfaces 176 and 182 of member 174 may be chosen to limit movement of engaging plate 106 relative to member 174. In certain embodiments, surface 182 of member 174 may be sloped relative to surface 176 to increase an area of contact between surface 182 and limiter 154. Surface 182 may be sloped to increase a range of motion between engaging plate 106 and member 174. In some embodiments, a slope of surface 182 may limit movement of engaging plate 106 relative to member 174. In certain embodiments, maximum extension allowed by implant 100 may range from about 3° to about 12°. In some embodiments, maximum extension allowed by implant 100 may be about 8°. In other embodiments, maximum extension allowed by implant 100 may be about 5°. Some implant embodiments may include a limiter designed to limit another component of motion of a disc implant. Other implant embodiments may include one or more additional limiters designed to limit other components of motion of a disc implant.

In certain embodiments, inner surface 112' of engaging plate 106 may contact surface 182 of member 174. Contact of inner surface 112' with surface 182 may limit flexion of vertebrae adjacent to engaging plates 102, 106. A distance between surfaces 176 and 182 of member 174 may be chosen to limit flexion between vertebrae adjacent to engaging plates 102, 106. Maximum flexion allowed by implant 100 may range from about 5° to about 20°. In some

embodiments, maximum flexion allowed by implant 100 may be about 10°. In other embodiments, maximum flexion allowed by implant 100 may be about 15°.

In certain embodiments, components of implant 100 may be coupled to one another. Coupling of components of implant 100 may allow partial assembly of the implant prior to a surgical procedure. In some embodiments, a manufacturer of implant 100 may at least partially assemble the implant prior to shipment. Some of the components of implant 100 may be held together during use, at least partially, by pressure resulting from the natural compression of the spine.

FIG. 18 depicts a perspective view of components of implant 100, including engaging plate 102, members 104 and 174, and engaging plate 106. FIG. 19 depicts a cross-sectional view of the implant shown in FIG. 18 after the implant has been assembled. As shown in FIGS. 18 and 19, engaging plate 102 may include projection 146 and opening 184. Projection 146 may be coupled to engaging plate 102. In some embodiments, projection 146 may be an integral part of engaging plate 102. A shape of projection 146 may be, but is not limited to being, round, square, rectangular or irregular. Projection 146 may complement recess 148 (shown in FIG. 19) in member 104. In certain embodiments, recess 148 may have a slightly larger cross section than projection 146 to allow engaging plate 102 to move relative to member 104. In some embodiments, recess 148 may have a cross section substantially equal to a cross section of projection 146 to inhibit rotation of engaging plate 102 relative to member 104.

In some embodiments, opening 184 may extend through engaging plate 102. In other embodiments, opening 184 may extend to a fixed depth in engaging plate 102. Opening 184 may be designed (e.g., threaded) to receive a coupling device such as coupler 186. Coupler 186 may be, but is not limited to being, a screw, a bolt or a pinch clamp. Coupler 186 may couple member 104 to engaging plate 102. During use, coupler 186 may extend through at least a portion of member 104 into opening 184 of engaging plate 102. A head of coupler 186 may be recessed in opening 188 of member 104. Coupler 186 may allow engaging plate 102 to move relative to member 104. In some embodiments, engaging plate 102 may rotate around axis of rotation 138 relative to first member 104 in the plane indicated by arrow 140 in FIG. 19. Relative movement of engaging plates 102, 106 may allow axial rotation of vertebrae adjacent to implant 100. Axis of rotation 138 may be offset from a center of engaging plates 102, 106 to imitate a longitudinal axis of rotation of a spine.

As shown in FIG. 18, member 104 may have convex portion 164. Convex portion 164 may have an arcuate cross-sectional shape along at least one axis. Member 174 may include recess 166. Recess 166 may have an arcuate cross section along at least one axis. Recess 166 may complement convex portion 164 of member 104, as shown in the side view of implant 100 in FIG. 20. In some embodiments, a thickness of engaging plate 102 proximate member 104 may exceed a thickness of the engaging plate at ends 168, 168' such that inner surfaces 112, 112" slope toward an outer surface of the engaging plate. In some embodiments, a slope of inner surface 112 may be different than a slope of inner surface 112". A thickness of member 174 proximate recess 166 may exceed a thickness of the member at ends 190, 190' such that surfaces 192, 192' of second member 174 slope away from engaging plate 102. In some embodiments, a slope of surface 192 may be different than a slope of surface 192'. In some embodiments, slopes of surfaces 192, 192' may be substantially the same magnitude as slopes of inner surfaces 112, 112", respectively.

Sloped surfaces 112, 112" may allow engaging plate 102 to move (e.g., rock) relative to member 104 in a mediolateral plane. Relative movement of engaging plates 102, 106 may allow lateral bending of vertebrae adjacent to the engaging plates in the plane indicated by arrow 136 in FIG. 18. Contact of surfaces 112, 112" and 192, 192', respectively, may distribute a compressive load applied to implant 100 over a relatively large area.

In some embodiments, member 174 may have convex portion 178. Convex portion 178 may have an arcuate cross-sectional shape. Engaging plate 106 may include recess 180. Recess 180 may be concave with an arcuate cross-sectional shape. Recess 180 may complement convex portion 178. Recess 180 may have a slightly larger cross section than convex portion 178 to allow engaging plate 106 to move (e.g., rock) toward engaging plate 102 as indicated by arrow 134 in FIG. 19. Movement of engaging plate 106 relative to member 174 may allow flexion and/or extension of vertebrae adjacent to engaging plates 102, 106.

Member 104 may include one or more stops 194 (shown in FIGS. 18 and 19). Stops 194 may be coupled to one or both ends of member 104. In some embodiments, stops 194 may be an integral part of member 104. Stops 194 may restrict anteroposterior translation of member 174 relative to member 104. Restriction of translation of member 174 relative to member 104 may facilitate positioning of implant 100 between vertebrae.

In certain embodiments, contact of stop 194 with inner surface 112' of engaging plate 106 may limit extension of vertebrae adjacent to implant 100. A height of stop 194 and/or a thickness of engaging plate 106 may limit extension allowed by implant 100. Maximum extension allowed by implant 100 may range from about 3° to about 12°. In some embodiments, maximum extension allowed by implant 100 may be about 8°. In other embodiments, maximum extension allowed by implant 100 may be about 5°.

Surface 182 of member 174 may be sloped relative to surfaces 192, 192' of the member. Inner surface 112' of engaging plate 106 may be sloped relative to an outer surface of the engaging plate. A slope of surface 182 and/or a slope of inner surface 112' may be chosen to increase a contact area between surface 182 and limiter 154 of engaging plate 106. A slope of surface 182 may be chosen to increase a range of motion between engaging plate 106 and member 174. In some embodiments, a shape and/or size of recess 180 may limit motion of engaging plate 106 relative to another component of the implant.

In certain embodiments, inner surface 112' of engaging plate 106 may contact surface 182 of member 174. Contact of inner surface 112' and surface 182 may limit flexion of the spine. A distance between surface 182 and surfaces 192, 192' of member 174 may be chosen to limit flexion between vertebrae adjacent to engaging plates 102, 106. Maximum flexion allowed by implant 100 may be from about 5° to about 20°. In some embodiments, maximum flexion allowed by implant 100 may be about 10°. In other embodiments, maximum flexion allowed by implant 100 may be about 15°.

In some embodiments, a first engaging plate may be substantially the same as a second engaging plate. Manufacturing costs may be reduced for implants with substantially equivalent engaging plates. FIG. 21 depicts a perspective view of implant 100 with substantially equivalent engaging plates 102. Member 104 may separate engaging plates 102. In certain embodiments, member 104 may have a rounded shape including, but not limited to, ovoid, spheroid and ellipsoid. Member 104 may be formed from metal (e.g., chrome) or ceramic. In certain embodiments, member 104 may be highly polished to inhibit wear. Engaging plates 102 may include concave portions 132. Concave portions 132 may complement member 104. A thickness of member 104 may exceed a cumulative depth of concave portions 132.

FIG. 22 depicts a cross-sectional view of the implant shown in FIG. 21 after the implant has been assembled. A separation of engaging plates 102 by member 104 may allow the engaging plates to "rock" relative to one another. Rocking of engaging plates 102 relative to one another in an anteroposterior plane may allow flexion and/or extension in the plane indicated by arrows 134. Rocking of engaging plates 102 relative to one another in a mediolateral plane may allow lateral bending in the plane indicated by arrows 136 in FIG. 21.

A shape of member 104 may provide a large contact area between the surface of member 104 and concave portions 132. A shape of member 104 may decrease wear and/or failure of implant 100. Concave portions 132 with an oval shape may allow member 104 to imitate the movement of a human spine around axis of rotation 138. Engaging plates 102 may freely rotate relative to one another around axis of rotation 138 in the plane indicated by arrow 140. In some embodiments, a position of axis of rotation 138 may change as member 104 translates in recesses 132. In an embodiment, a range of motion (e.g., axial rotation) may be limited by the shape of member 104 and/or the shape of concave portion 132.

In an embodiment, an inner surface of engaging plates 102 proximate concave portions 132 may be elevated. An elevation of one or more surfaces 196A-196D (shown in FIG. 21) may be chosen to limit relative movement of engaging plates 102. One or more surfaces 196A-196D may be sloped relative to outer surfaces of engaging plates 102 as shown in FIGS. 21 and 22. Slopes of surfaces 196A-196D may increase a contact area between engaging plates 102. Increasing a contact area between engaging plates 102 may inhibit wear of the implant.

In certain embodiments, surfaces 196D may limit flexion of vertebrae adjacent to the spinal implant. Surfaces 196B may limit extension of vertebrae adjacent to implant 100. Surfaces 196A and 196C may limit lateral bending of vertebra adjacent to implant 100. In some embodiments, axial rotation of engaging plates 102 relative to each other may be limited.

In some embodiments, an implant may be curved to accommodate radial curvature of vertebrae. Implants may be provided with varying amounts of radial curvature. For example, disc implants may be provided with large, medium and/or small radial curvatures. An indication of an amount of radial curvature provided by an implant may be etched or otherwise marked on the implant.

In some disc implant embodiments, engaging plates may be sloped to establish a desired lordotic curvature of a spine. Several different implant components with differing lordotic curvatures may be available to a surgeon so that the surgeon can form an implant with a desired lordotic angle. Lordotic indications may be etched or otherwise marked (e.g., color coded) on the disc implant to indicate the amount of lordosis that the implant will provide. In an embodiment, a lumbar disc implant may have a lordotic angle range of about 5° to about 20° (e.g., about 12°).

An engaging plate may be designed to promote coupling of the engaging plate to a vertebral surface. Coupling engaging plates of an implant to adjacent vertebrae may stabilize the disc implant. An engaging plate may include one or more coupling projections to facilitate coupling of the engaging plate to a vertebra. A coupling projection may extend from an outer surface of an engaging plate. Coupling projections may be, but are not limited to being, press fit, welded, glued or otherwise affixed to an engaging plate. Alternatively, coupling projections may be formed as part of an engaging plate. Any combination of coupling projections 108 may be used together to ensure stability of implant 100.

An engaging plate may include one coupling projection 108, as shown, for example, in FIGS. 9-11. FIG. 23 depicts a view of engaging plate 102 with two coupling projections 108. In some embodiments, an engaging plate may include a plurality of coupling projections 108, as shown in FIGS. 24 and 25. In some embodiments, an engaging plate may include coupling projections of substantially the same shape and size. In certain embodiments, an engaging plate may include coupling projections of different sizes and/or shapes. A shape and/or size of a coupling projection may be chosen based on factors including, but not limited to, durability, distribution of load and ease of forming a complementary recess in a vertebra.

In certain embodiments, a coupling projection extending from an engaging plate may be positioned in a recess formed in a vertebra. The recess may complement the coupling projection. Coupling projection 108 may have an arcuate cross section, as depicted, for example, in FIGS. 9-11. In some embodiments, a coupling projection may have a

square or rectangular cross section. FIG. 26 depicts a view of coupling projection 108 with a rectangular cross section. In certain embodiments, a coupling projection may be tapered in one or more directions. Coupling projection 108 shown in FIG. 27 is tapered in an anteroposterior direction. A tapered coupling projection may allow the coupling projection to be wedged into a recess in a bone to secure the engaging plate to the bone. Wedging the coupling projection in the recess may inhibit movement of the engaging plate relative to the vertebra and/or expulsion of the engaging plate from the bone. In some embodiments, surfaces of the coupling projection that are to be positioned adjacent to bone may be roughened or include a coating (e.g., hydroxyapatite) to promote osseointegration of the coupling projection with the bone. In some embodiments, coupling projections, such as those depicted in FIGS. 1, 24 and 25, may penetrate adjacent bone to inhibit movement of the engaging plate relative to the vertebra and/or to inhibit expulsion of the engaging plate from the bone.

In some embodiments, one or more coupling projections may be oriented substantially in an anteroposterior plane to facilitate implant insertion using an anterior approach. In some embodiments, one or more coupling projections may be oriented substantially in a mediolateral plane to facilitate implant insertion using a lateral approach. In certain embodiments, combinations of coupling projections of various cross-sectional shapes, such as those depicted in FIG. 1 may be used to inhibit movement of the engaging plate relative to the vertebra and/or expulsion of the engaging plate from the bone.

In some embodiments, a fastening system may be used to couple an implant to a vertebra. The implant may include a tab with an opening in a face of the tab. The opening may engage or couple to a head of a bone fastener. A fastening system may include a fastener and a locking mechanism. The locking mechanism may be positioned between the implant and the fastener. The locking mechanism may inhibit backout of the fastener from the vertebra and from the implant. In some embodiments, the locking mechanism may be a ring positioned in an opening in the implant. When the ring is in the opening, a head of the fastener inserted through the ring may contact the ring if the fastener begins to back out of the opening. The ring and fastener head combination may be too large to exit the opening, thereby inhibiting backout of the fastener from the vertebrae and from the implant. When the ring is positioned in the opening, the ring may lock to the fastener head without locking to the implant, thus allowing the plate to be securely tightened to the vertebra. U.S. Patent No. 6,454,769 to Wagner et al. and U.S. Patent No. 6,331,179 to Freid et al. describe fastening systems including locking mechanism for inhibiting backout of fasteners.

In certain embodiments, one or more instruments may be used to insert and/or position a disc implant between adjacent vertebrae after a discectomy has been performed. An inserter may be used to position an implant in a prepared disc space between adjacent vertebrae. The inserter may be sufficiently long to allow placement of a distal end of the inserter in the disc space from above an incision in a patient. Engaging plates of an implant may be coupled to arms at the distal end of the inserter.

FIG. 28 depicts a perspective view of an embodiment of inserter 210. Inserter 210 may include body 212 and arms 214. Body 212 may have opening 216. Opening 216 may be sized to allow one or more guidance, insertion and/or removal instruments to be positioned in inserter 210. Arms 214 may include extensions 218 for coupling inserter 210 to engaging plates of an implant. Extensions 218 may be chamfered, rounded, dovetailed or otherwise machined to engage slots 114 in engaging plates 102, 106 (shown in FIG. 1). Extensions 218 may include detents 220. Detents 220 may be positioned in indents 118 of engaging plates 102, 106 to couple inserter 210 to an implant. FIG. 29 depicts extensions 218 coupled to engaging plates 102, 106.

Portions of arms 214 may be angled relative to each other to establish a tapering separation distance between the arms. The angled portions of arms 214 may facilitate insertion of instruments that establish a desired separation distance between engaging plates 102, 106 attached to inserter 210.

Arms 214 may include mechanisms 222. FIG. 30 depicts a perspective side-view of inserter 210 that shows mechanisms 222 on arms 214. As depicted in FIG. 28, inserter 210 may include slots 224. Slots 224 may extend through arms 214 and extensions 218 from the mechanism 222 to a portion of the inserter near detents 220. Slots 224 may allow section 226 of inserter 210 to bend. Pressing mechanisms 222 may move section 226 and allow disengagement of detents 220 from indents located in engaging plates. When mechanisms 222 are pressed, detents may be disengaged from indents in engaging plates to separate inserter 210 from the engaging plates. In some embodiments, arms 214 may include reinforcement members 228 that stabilize portions of the inserter that are not able to move when mechanisms 222 are pressed. Reinforcement members 228 may limit outward movement of sections 226.

A proximal end of inserter 210 may be formed to engage a driving instrument or a guidance instrument, such as a slap hammer or a pusher. Slots 230 in a proximal end of inserter 210 (shown in FIG. 28) may be machined or otherwise designed to receive a coupling device such as coupler 232 shown in FIG. 31. FIG. 31 depicts a perspective view of inserter 210 coupled to slap hammer 234. Coupler 232 may engage an attachment mount of a driving instrument or a guidance instrument. Slap hammer 234 may include attachment mount 236. Coupler 232 may couple attachment mount 236 to inserter 210.

During some implant insertion procedures, an intervertebral space may be too small to allow insertion of implant components coupled to an inserter without scarring the surfaces of adjacent vertebrae. Shims may be placed adjacent to the vertebrae. Engaging plates coupled to an inserter may be positioned next to the shims. The inserter may be driven downwards to separate the vertebrae and insert the engaging plates between the vertebrae. After insertion of the engaging plates, the shims may be removed.

In some embodiments, a distractor may be used to separate adjacent vertebrae and/or to separate engaging plates to allow insertion of a member between the engaging plates. FIG. 32 depicts a perspective view of an embodiment of a distractor. Distractor 238 may include body 240, arms 242 and attachment mount 244. Body 240 and arms 242 may include grooves 246. Grooves 246 may be slightly larger in cross-section than projections 128 of member 104 (shown in FIG. 1). Projections 128 of member 104 may fit in grooves 246 to allow member 104 to be guided through body 240 and arms 242 to a position between engaging plates.

In some embodiments, grooves 246 may be sized and/or shaped to accept only a particular sized member of an implant. For example, a member for a 13 mm implant will not fit in a distractor that establishes a separation distance sized for an 11 mm implant. In some embodiments, members and distractors may be color coded substantially the same color. A surgeon may know to only put a member into a distractor of substantially the same color.

In certain embodiments, arms 242 may include reinforcement member 248. Reinforcement member 248 may inhibit movement of arms 242 during insertion of a member between engaging plates to form an implant.

Slots 250 on attachment mount 244 may be machined to receive a coupler. A coupler may couple distractor 238 to a drive instrument, such as a slap hammer.

FIG. 33 depicts a perspective view of distractor 238 positioned in inserter 210. Arms 242 may separate arms 214 of inserter 210. As arms 214 are separated by distractor 238, engaging plates 102, 106 are separated. Slots in engaging plates 102, 106 and arms 242 may separate arms 214 such that the engaging plates remain substantially parallel during the separation process. Engaging plates 102, 106 may remain substantially parallel during insertion of a member between the engaging plates. Separation of arms 214 with distractor 238 may minimize or eliminate contact of the distractor with engaging plates 102, 106. Minimizing or eliminating contact of distractor 238 with engaging plates 102, 106 during distraction may inhibit undesired separation of the engaging plates from the inserter 210.

FIG. 34 depicts a perspective view of an embodiment of a pusher. Pusher 252 may include body 254 and attachment mount 256. A width of a distal end of body 254 may be less than a width of a proximal end of the body. Body 254 may include projections 258. Projections 258 may fit in grooves 246 of distractor 238 (shown in FIG. 32) to allow pusher 252 to be guided through body 240 and arms 242 of the distractor. In some embodiments, pushers may be color coded to match to a particular size of distractor. In some embodiments, projections 258 may be sized so that the pusher fits in any size of distractor.

Pusher 252 may be used to move a member through distractor 238 to a desired position between engaging plates. FIG. 35 depicts a side view of an embodiment of pusher 252 positioned in distractor 238 and inserter 210. When pusher 252 is positioned in inserter 210, the pusher may maintain a position of a member between engaging plates 102, 106 and allow for removal of distractor 238 from the engaging plates.

During some implant insertion procedures, a channel or channels may be formed in vertebrae. The channel or channels may correspond to a coupling projection or coupling projections of engaging plates. Instrument guides may be used to facilitate formation of a channel or channels in vertebrae. In some embodiments, two instrument guides may be coupled to an inserter. The instrument guides may be inserted into a disc space. A distractor may be introduced into the inserter to move the instrument guides against vertebrae. Channels may be formed in the vertebrae using instruments in combination with the instrument guides.

FIG. 36 depicts a perspective view of instrument guide 260. Instrument guide 260 may include slots 261, stops 262, and guide piece 264. Slots 261 may allow instrument guide 260 to be coupled to extensions of arms of an inserter. Stops 262 may limit an insertion depth of instrument guide 260 between vertebrae. Stops 262 may have openings 266. Fasteners may be positioned through openings 266 to secure instrument guide 260 to a vertebra during formation of a channel or channels in the vertebra. The fasteners may include, but are not limited to, screws, pins, barbs, or trocars. A head of a fastener may be too large to pass through opening 266.

Guide piece 264 may be used to place a cutting edge of an instrument (e.g., chisel, drill, reamer) at a desired location relative to a vertebra. The instrument may be passed through guide piece opening 268. Guide piece opening may properly orient a cutting portion of the instrument relative to a vertebra that the instrument is to form a channel in. A portion of the instrument may be positioned in groove 270 to guide the cutting edge of the instrument during formation of a channel in the vertebra. As the instrument travels along groove 270, bone matter may be removed from the vertebral surface adjacent to instrument guide 260 to form a groove in the vertebra. Bone matter may be removed to form an opening of a length and/or depth similar to a cross-sectional shape of a coupling projection on an engaging plate.

FIG. 37 depicts a perspective view of distractor 238, driver 272 and instrument guides 260 coupled to inserter 210. Driver 272 may position a shaft of fastener 274 through an opening in stop 262 so that the fastener couples instrument guide 260 to the vertebra.

FIG. 38 depicts a top view of chisel 276. FIG. 38A depicts a side view of chisel 276. Chisel 276 may include end member 278, shaft 280 and handle 282. End member 278 may include a cutting edge capable of penetrating bone. In some embodiments, shaft 280 may be bent to accommodate an angle between a proximal portion of an inserter and a channel guide positioned between vertebrae.

FIG. 39 depicts a perspective view of instrument guides 260, distractor 238, and chisel 276 coupled to inserter 210. End member 278 of chisel 276 may be inserted through a guide piece opening in guide piece 264 and positioned in groove 270 of instrument guide 260. Cutting edges of end member 278 may be forced into a vertebra. Insertion depth of end member 278 into the vertebra may be monitored using fluoroscopic imaging. In some embodiments, shaft 280 may be marked with a scale. When the end member of the chisel first contacts the vertebra, a first reading of the scale relative

to a top of the inserter may be taken. As the chisel is driven into the vertebra, an estimate of the insertion depth may be provided by taking the difference between the current scale reading relative to the top of the inserter and the first reading of the scale relative to the top of the inserter. In some embodiments, a stop may be positioned on shaft 280 to limit insertion depth of the chisel into a vertebra. The stop may contact guide piece 264.

FIG. 40 depicts a perspective view of a reamer in combination with inserter 210, distractor 238 and instrument guides 260. Reamer 284 may allow removal of bone matter from a vertebral surface to form a groove in the vertebral surface. The groove may have an arcuate cross-sectional shape to complement an arcuate shaped coupling projection on an engaging plate (as shown in FIGS. 9-11). Reamer 284 may include cutter 286, body 288 and handle 290. In some embodiments, a drive shaft may be positioned in body 288. The drive shaft may be coupled to cutter 286 and to handle 290. The drive shaft may be flexible or include flexible joints so that cutter 286 will be oriented in a proper direction relative to the inserter and the vertebra. Cutter 286 may be inserted in an opening of guide piece 264 of instrument guide 260. Rotation of handle 290 may allow cutter 286 to remove vertebral bone and form a groove in the vertebra. Contact of stop 292 with guide piece 264 may limit an insertion depth of cutter 286 into the vertebra. A position of stop 292 along body 288 may be adjustable. In some embodiments, insertion depth of cutter 286 into the vertebra may be monitored during formation of the groove using fluoroscopic imaging.

In certain embodiments, a trial spacer may be used during formation of a disc space between vertebrae. A trial spacer may be used to determine when an appropriate sized disc space is formed between vertebrae. The trial spacer may also determine a size of trial endplates and/or engaging plates. FIG. 41 depicts embodiments of trial spacers 294. A distal end of trial spacer 294 may be similar in size (e.g., small, medium or large) to engaging plates and/or trial endplates.

During some implant insertion procedures, trial endplates may be used to determine the proper height and lordotic angle of the implant to be inserted into the patient. Top surfaces of the trial endplates may be smooth and/or polished so that the trial endplates easily slide between vertebrae. FIG. 42 depicts a bottom view of trial endplate 296. Trial endplate 296 may include slots 114 to engage extensions of arms of an inserter. Slots 114 may include indents 118. Indents 118 may engage detents of an inserter to securely couple the inserter to trial endplate 296.

Trial endplates 296 may vary in thickness. For example, a thickness of trial endplate 296 at an edge near slots 114 may exceed a thickness of the trial endplate at an edge opposite the slots. Trial endplates 296 may have slopes ranging from about 2° to about 22° (e.g., about 3°, about 6°, about 9°, about 12°). The combined angle of a top trial endplate and a bottom trial endplate may determine the lordotic angle that will be established by engaging plates of an implant that correspond to the trial endplates. For example, if two trial endplates with 3° of slope are used, an implant formed between the vertebrae may be formed with two engaging plates, each engaging plate having 3° of slope. The formed implant may establish a 6° lordotic angle between the vertebra. If the top trial endplate has 3° of slope and the bottom trial endplate has 6° of slope, an implant formed between the vertebrae may be formed with a top engaging plate having a 3° slope and a bottom engaging plate having a 6° slope. The formed implant may establish a 9° lordotic angle between the vertebrae.

An instrumentation kit for an implant insertion procedure may include individual trial endplates that correspond in height and slope to each engaging plate supplied in the instrumentation kit. If more than two engaging plates of the same size and slope are supplied in the instrumentation set, only two trial endplates corresponding to that size and slope engaging plate are needed in the instrumentation set. Having a trial endplate that corresponds to each engaging plate allows a surgeon to insert trial endplates that correspond to available engaging plates between the vertebrae. The surgeon is able to test every combination of implant that can be formed using the trial endplates supplied in the instrumentation

kit. The surgeon can test an exact model of the implant that is to be formed in the disc space by choosing the appropriate trial endplates and distractor.

When the trial endplates are coupled to an inserter and positioned in the disc space, a distractor may be positioned in the inserter to separate the trial endplates. If the distractor easily slides into the inserter, a larger distractor may be tried. If the distractor cannot be inserted into the inserter, a smaller distractor may be tried. If some force is needed to insert the distractor into the inserter, the distractor may be the appropriate distractor. An appropriate distractor may overdistract vertebrae by about 1.5 mm to about 2.0 mm. Overdistraction of vertebrae by about 1.5 mm to about 2.0 mm may extend ligaments proximate the vertebrae sufficiently to allow for relative movement of components of a disc implant once the implant has been inserted. A fluoroscopic image may be obtained to determine if the trial endplates establish desired lordosis and height between the vertebrae. If the lordosis or height is not correct, other trial endplates and/or distractors may be coupled to the inserter. The inserter may be positioned between the vertebra until the trial endplates and distractor establish a desired height and lordotic angle between the vertebrae. Engaging plates that correspond to the trial endplates and a member that will slide down the distractor may be obtained from the instrumentation kit.

FIG. 43 depicts perspective view of a member seater. Member seater 298 may facilitate seating of a member of an implant between engaging plates. Member seater 298 may include arms 300, 300' and handles 302, 302'. Arms 300, 300' may be pivotally coupled to handles 302, 302'. Arm 300' may be positioned on a topside of projection 128 of member 104 (depicted in FIG. 1). Arm 300' may engage slots 114 of engaging plate 102 (depicted in FIG. 1). Compression of handle 302 in the direction of handle 302' may allow arm 300' to move toward arm 300. Movement of arm 300' toward arm 300 may allow member 104 to be securely positioned in recess 116 of engaging plate 102. After seating member 104, member seater 298 may be removed from the intervertebral space.

Engaging plates, members and/or trial endplates may be made of one or more biocompatible materials including, but not limited to, metals, alloys, ceramics, polymers and/or composites. For example, an alloy may include cobalt-chrome-molybdenum (CoCrMo). Ceramics may include, but are not limited to, alumina, zirconia or composites. Polymers used for implant components may include ultra-high molecular weight polyethylene, polyfluorocarbons and/or polyesteresterketone (PEEK). In some embodiments, all components of a disc implant may be formed of metal. In certain embodiments, engaging plates and/or members may be formed of titanium, titanium alloys, steel and/or steel alloys. In addition, materials may be chosen based upon characteristics such as durability and ease with which biological tissue, such as human bone, fuse with the material. For example, titanium may wear poorly over time, but may fuse well with bone. A cobalt-chrome-molybdenum alloy may wear well, but may not fuse as well with biological tissue.

In some embodiments, engaging plates and/or members may be or may include bioabsorbable material. Surfaces of engaging plates and/or members that contact bone may include a coating to promote osseointegration of the implant component with bone. The coating may be, but is not limited to, a bone morphogenic protein, hydroxyapatite and/or a titanium plasma spray.

In certain embodiments, engaging plates, members and/or trial endplates of an implant may be formed of different materials to decrease wear of the implant over time. An implant embodiment may include engaging plates formed of titanium or cobalt-chrome-molybdenum and one or more members formed of ceramic (such as alumina) or polymer (such as ultra-high molecular weight polyethylene). Material choice may be influenced by various factors. For example, many polymers tend to "flow" when they are produced at less than a certain thickness, possibly deforming and leading to the failure of an implant. Ceramics, however, do not tend to deform, but may potentially shatter under pressure.

In certain embodiments, an implant and/or trial endplates may be distributed and/or sold pre-assembled and stored in sterile packaging until needed. In some implant embodiments, radiological markers may be placed in components of an implant that are invisible to x-rays. The radiological markers may allow the position of the component to be determined using x-rays or other imaging techniques. The ability to determine the position of all components of an implant may eliminate a need to have a surgical procedure to determine the location of the implant.

In some embodiments, steps may be taken to adjust the coefficient of friction of materials used to form engaging plates, members and/or trial endplates. Implant components may be machined, formed and/or chemically treated to decrease the coefficient of friction and reduce the amount of wear on engaging plates and/or members. In some implant embodiments, an insert, coating, liner or other covering may be placed on all, or a portion, of a surface of the engaging plates and/or members. The insert, coating, liner or covering may modify frictional or other physical properties of an engaging plate and/or member relative to another component of an implant. In some embodiments, a surface of a member and/or an inner surface of an engaging plate may include a surface coating to reduce noise resulting from contact between implant components.

An implant may be positioned in an intervertebral space between adjacent vertebrae using an anterior, lateral and/or posterior approach. A surgeon may perform a discectomy to remove all or a portion of an intervertebral disc. Instruments such as curettes, rongeurs and bone shavers may be used to prepare the disc space for the implant. Vertebral surfaces that will contact engaging plates of an implant may be cleaned of cartilage or other tissue. The vertebral surfaces may be shaped to substantially conform to outer surfaces of engaging plates to be placed against the vertebral surfaces.

In an implant insertion procedure, trial spacers may be inserted in the intervertebral space to determine if a formed disc space is sufficiently large and/or to determine a size of an implant to be inserted in the disc space (e.g., small, medium or large). Radiological images may be taken during the discectomy with a trial spacer positioned between the vertebrae to determine if a disc space of the proper width and depth has been formed. One or more marks may be scored or burned into a surface of a vertebra close to a center of an edge of the vertebra. The mark or marks may be used as references to determine a proper lateral position of the implant and/or instrumentation during insertion of the implant.

If needed, instrument guides may be positioned against vertebrae. A reamer or a chisel may be used in conjunction with the instrument guides to form recesses in the vertebrae. The recess may have a shape that conforms to a shape of a coupling projection that extends from an engaging plate of an implant to be positioned between vertebrae.

Trial endplates may be coupled to an inserter. The trial endplates may be positioned between the vertebrae. A distractor of a determined height may be positioned in the inserter to separate the trial endplates. During some insertion procedures, a mallet or other impact device may be used to drive the distractor into the inserter. If the trial endplates and distractor combination do not establish a desired separation height and/or lordotic angle between the vertebrae, different trial endplates and/or different distractors may be tested until a combination of trial endplates and distractor is found that establishes the desired separation height and lordotic alignment of the vertebrae. If removal of trial endplates from a disc space is difficult, a slap hammer or other impact device may be used to facilitate removal of the inserter and trial endplates from the disc space. Using various combinations of trial endplates and distractors may allow a surgeon to determine the correct lordotic angle and height of implant components to be inserted in the intervertebral space.

Engaging plates that correspond to trial spacers that establish a desired separation height and lordotic angle may be chosen from available engaging plates supplied in an instrumentation kit. The chosen engaging plates may be coupled to arms of an inserter. The engaging plates may be positioned in the disc space. The chosen distractor may be positioned in the inserter. During some insertion procedures, a mallet or other impact device may be used to drive the distractor into

the inserter. Positioning the distractor in the inserter may separate engaging plates attached to the arms to a desired separation distance. Separation of the engaging plates may force coupling projections of the engaging plates into surfaces of adjacent vertebrae to anchor the engaging plates to the bone.

A member that will slide down channels of the distractor may be obtained from the instrumentation set. The member may be positioned in the distractor and guided between engaging plates with a pusher. The pusher may be coupled to the inserter to maintain a position of the member between the engaging plates. After the member is positioned between the engaging plates, a mechanism on the arms of the inserter may be engaged to release the extension on the arms from the engaging plates. The inserter, distractor and pusher may be removed from the disc space. During some insertion procedures, a slap hammer may be used to facilitate removal of the inserter, distractor and/or pusher from the disc space. Radiological images may be taken to ensure that the implant is positioned as desired.

During some insertion procedures, a member seater may be used after an inserter has been removed from the engaging plates. The member seater may be positioned on a projection of a member and in a slot of an engaging plate. Handles of the member seater may be compressed to securely seat the member in a recess of the engaging plate. The handles may be released to disengage the arms from the projections and from the engaging plate. The member seater may be removed from the intervertebral space.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as examples of embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

WHAT IS CLAIMED IS:

1. An artificial disc implant for a human spine, comprising:
two engaging plates, wherein each engaging plate comprises:
a recess; and
two or more slots configured to engage an insertion instrument during insertion of the disc implant,
wherein the slots are at an angle relative to an anterior-posterior axis of the engaging plates; and
one or more members positionable between the engaging plates, wherein at least one of the members comprises
a portion configured to complement at least one of the recesses to allow axial rotation, lateral movement and
anteroposterior movement of the engaging plates relative to each other during use.
2. The implant of claim 1, wherein one or more sides of at least one of the recesses are tapered.
3. The implant of claim 1, wherein a height of a posterior side exceeds a height of an anterior side of at least one of the recesses.
4. The implant of claim 1, wherein the portion configured to complement at least one of the recesses is a convex portion, and wherein at least one of the recesses comprises a concave portion complementary to the convex portion.
5. The implant of claim 1, wherein at least one of the engaging plates comprises a convex portion, wherein at least one of the members comprises a concave portion, and wherein the convex portion is complementary to the concave portion.
6. The implant of claim 1, wherein the two engaging plates and the one or more members are made of metal.
7. The implant of claim 1, wherein the slots are dovetailed.
8. A system for inserting an artificial disc implant between human vertebrae, comprising:
an inserter having a body, a passage through the body, and arms, wherein the arms are configured to be
releasably coupled to engaging plates of the artificial disc implant; and
a distractor positionable in the passage in the body, wherein the distractor is configured to separate the arms of
the inserter such that engaging plates coupled to the arms of the inserter remain substantially parallel during separation of
the engaging plates to form a disc space between the human vertebrae.
9. The system of claim 8, wherein the inserter is configured such that coupling the inserter to the engaging plates
does not increase separation between the engaging plates.
10. The system of claim 8, wherein the arms of the inserter are configured to be releasably coupled to dovetailed
slots in the engaging plates.

11. The system of claim 8, wherein the inserter and the distractor are configured such that the distractor does not contact the engaging plates during insertion of the engaging plates.
12. The system of claim 8, further comprising a pusher, wherein the pusher is configured to drive a member through a passage in the distractor and position the member between the engaging plates.
13. The system of claim 8, further comprising a member seater configured to seat a member in the engaging plates through the passage in the inserter.
14. The system of claim 8, further comprising trial endplates and one or more additional distractors, wherein the trial endplates are configured to be used in combination with the distractors to determine height and lordotic angle of the artificial disc implant to be inserted.
15. A method for forming an artificial disc implant between human vertebrae, comprising:
 - positioning two engaging plates between the human vertebrae;
 - separating the engaging plates such that the engaging plates remain substantially parallel;
 - positioning one or more members between the engaging plates such that a surface of at least one of the members contacts a complementary surface of at least one of the engaging plates; and
 - wherein the engaging plates and at least one of the members are configured to allow relative movement of the engaging plates during use.
16. The method of claim 15, further comprising determining a height, size and lordotic angle of the artificial disc implant to be formed between the vertebrae before positioning the engaging plates between the vertebrae.
17. The method of claim 15, further comprising forming a recess in at least one of the vertebrae to engage a projection on at least one of the engaging plates.
18. The method of claim 15, wherein positioning at least one of the members comprises positioning such members in a rounded recess in at least one of the engaging plates.
19. The method of claim 15, wherein the engaging plates are positioned using an angulated anterior approach to the vertebrae.
20. The method of claim 15, wherein the engaging plates are positioned using an anterior approach to the vertebrae.
21. A disc implant, comprising:
 - a first engaging plate and a second engaging plate;
 - a member positionable between the engaging plates;
 - wherein the first engaging plate comprises a recess configured to receive a base of the member, wherein one or more sides of the recess are tapered; and

wherein a surface of the second engaging plate complements a surface of the member to allow axial rotation, lateral movement and anteroposterior movement of the engaging plates relative to each other during use.

22. The implant of claim 21, wherein a height of a posterior side of the recess is greater than a height of an anterior side of the recess.
23. The implant of claim 21, wherein at least one of the engaging plates comprises a concave portion complementary to a convex portion of the member.
24. The implant of claim 21, wherein at least one of the engaging plates comprises a convex portion complementary to a concave portion of the member.
25. The implant of claim 21, wherein at least one of the engaging plates comprises at least one coupling projection.
26. The implant of claim 21, wherein the engaging plates comprise one or more slots, wherein the slots are configured to engage an instrument for insertion of the implant.
27. The implant of claim 21, wherein the engaging plates comprise one or more slots wherein the slots are configured to engage an instrument for insertion of the implant and wherein the slots are positioned at an angle relative to anterior-posterior axes of the engaging plates.
28. A system for inserting an artificial disc implant, comprising:
 - an inserter having a body, a passage through the body and arms, wherein the arms are configured to be releasably coupled to engaging plates of the artificial disc implant; and
 - one or more distractors positionable through the passage in the body, the distractors configured to move the arms to establish a separation distance between engaging plates coupled to the arms.
29. The system of claim 28, further comprising a pusher configured to drive a member down a passage through the distractor to a position between the engaging plates.
30. The system of claim 28, further comprising a member seater configured to seat a member between the engaging plates.
31. The system of claim 28, further comprising trial endplates, wherein the trial endplates in combination with at least one distractor are configured to determine height and lordotic angle of the artificial disc implant to be inserted.
32. An instrument kit, comprising:
 - one or more trial endplates;
 - a plurality of implant components; and
 - an inserter configured to couple to selected implant components to allow the components to be positioned in a disc space;

one or more distractors configured to couple to the inserter to establish a separation distance between the selected implant components coupled to the inserter.

33. The instrument kit of claim 32, wherein the inserter is configured to couple to the trial endplates.
34. The instrument kit of claim 32, wherein one or more of the trial endplates are sloped.
35. The instrument kit of claim 32, further comprising a pusher configured to position an implant component between the selected implant components coupled to the inserter.
36. The instrument kit of claim 32, further comprising a member seater, wherein the member seater is configured to apply pressure to one of the implant components.
37. The instrument kit of claim 32, further comprising a pusher configured to position an implant component between the selected implant components coupled to the inserter.
38. A method for forming an implant between vertebrae of a spine, comprising:
coupling a pair of engaging plates to a portion of an inserter;
positioning the engaging plates between adjacent vertebrae;
positioning one or more members between the engaging plates; and
wherein at least a portion of the engaging plates and at least a portion of at least one member is configured to allow at least some movement of a first vertebra relative to a second vertebra.
39. The method of claim 38, wherein positioning the engaging plates comprises an anterior approach to the vertebrae.
40. The method of claim 38, wherein positioning the engaging plates comprises an angled anterior approach to the vertebrae.
41. The method of claim 38, further comprising positioning a distractor in the inserter wherein the distractor is configured to separate in a substantially parallel direction one engaging plate from a second engaging plate.
42. The method of claim 38, further comprising positioning a distractor in the inserter wherein the distractor is configured to separate one engaging plate from a second engaging plate and wherein positioning a member of the one or more members between the engaging plates comprises guiding the member through the distractor with a pusher.
43. The method of claim 38, wherein the movement comprises at least axial rotation and lateral movement of the spine.

44. The method of claim 38, further comprising inserting one or more trial implants and one or more distractors in the vertebral space before coupling the engaging plates to the inserter to determine a lordotic angle of the engaging plates and a height of the members to be inserted.

45. An instrument for insertion of a disc implant, comprising:
a body;
one or more arms configured to couple to one or more engaging plates;
a distractor positionable in an opening of the body, wherein the distractor is configured to separate in a substantially parallel direction one engaging plate from a second engaging plate.

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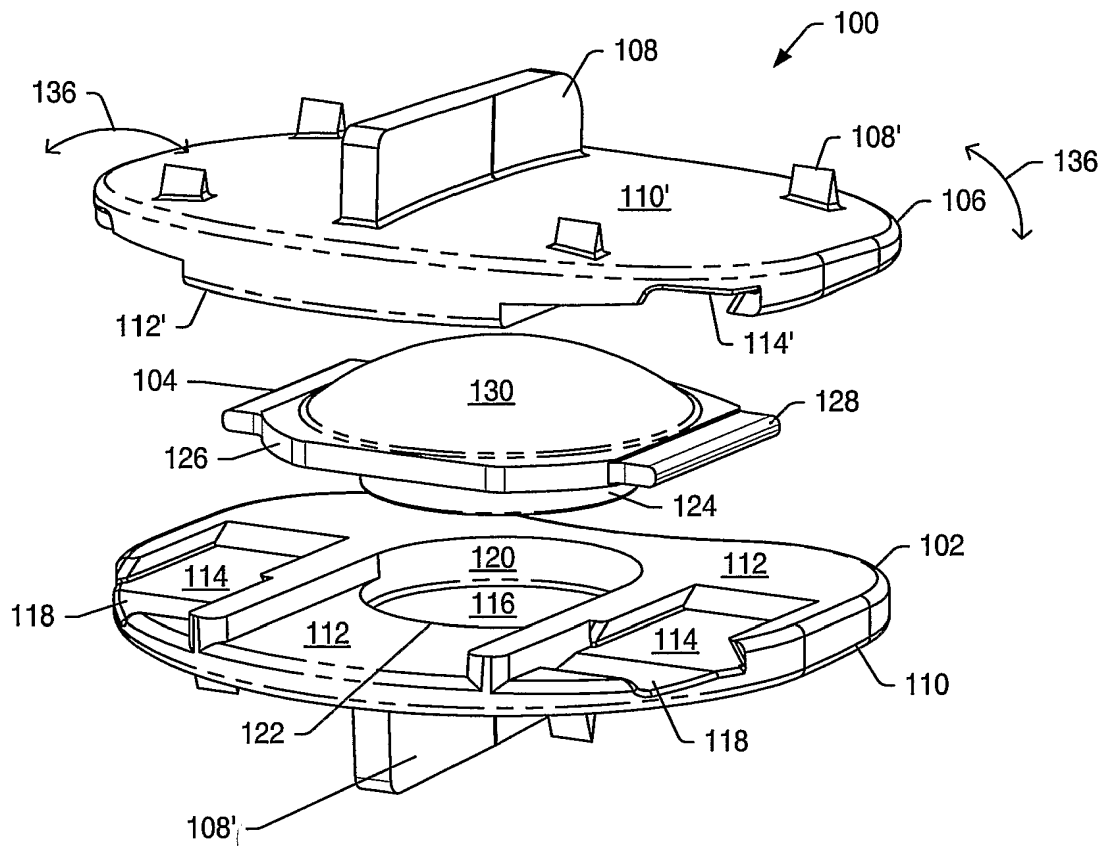


FIG. 1

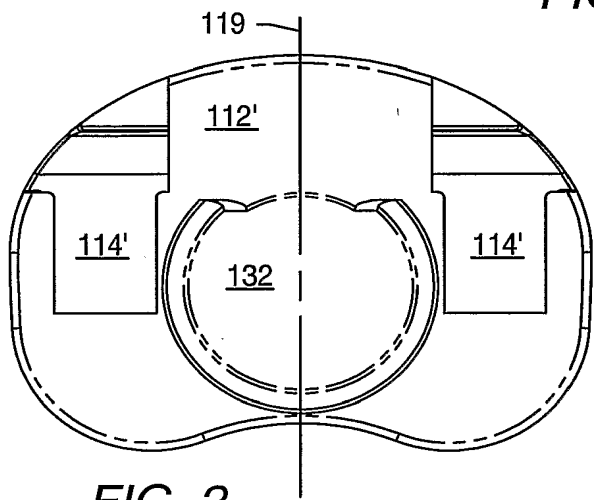


FIG. 2

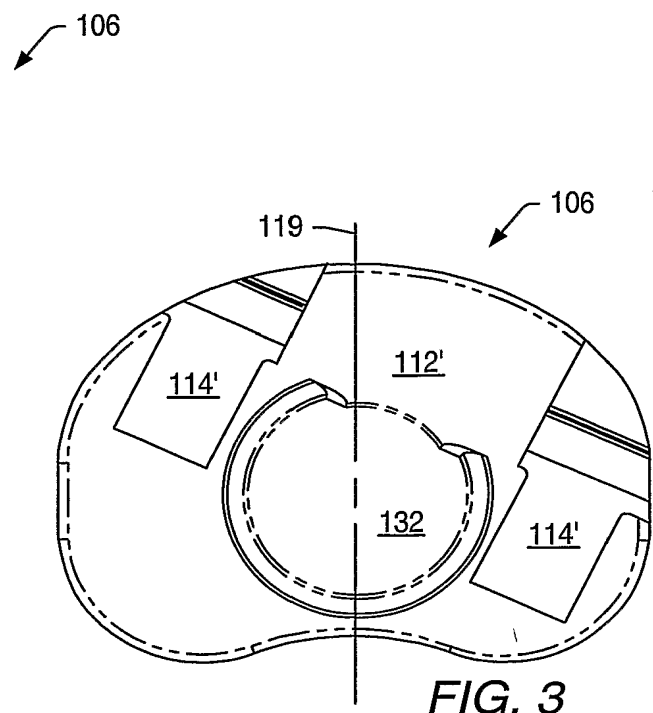
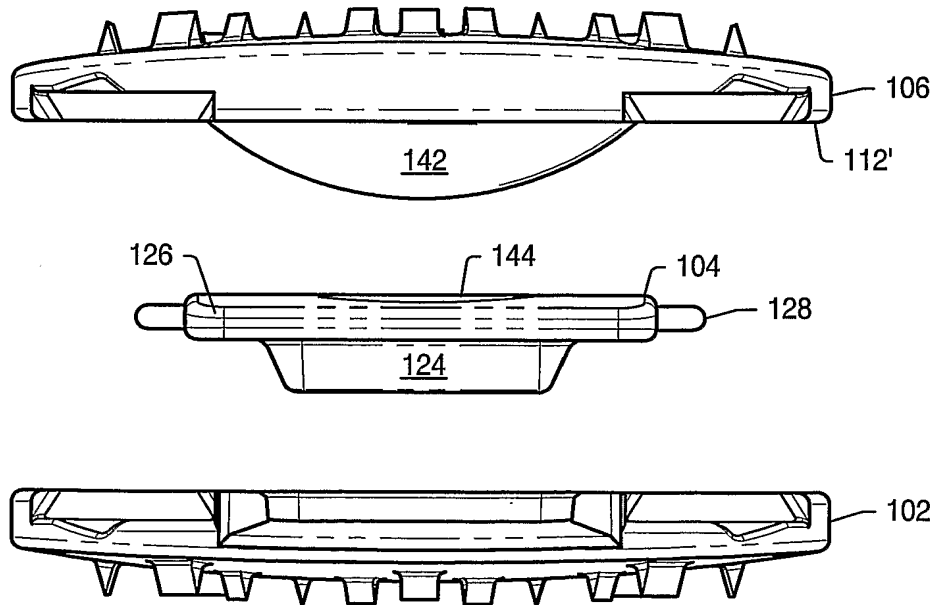
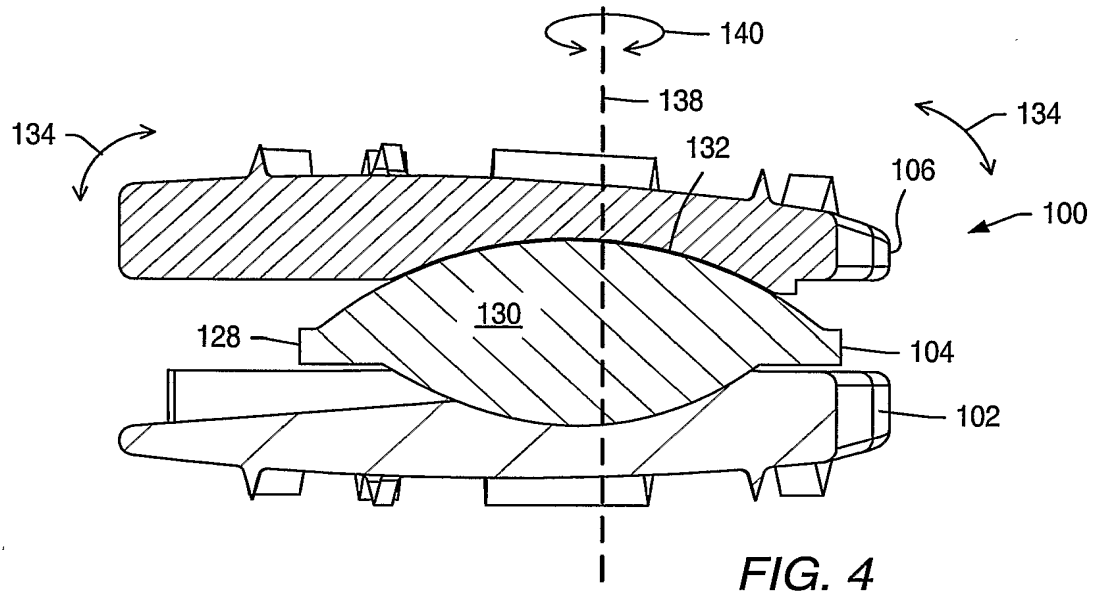
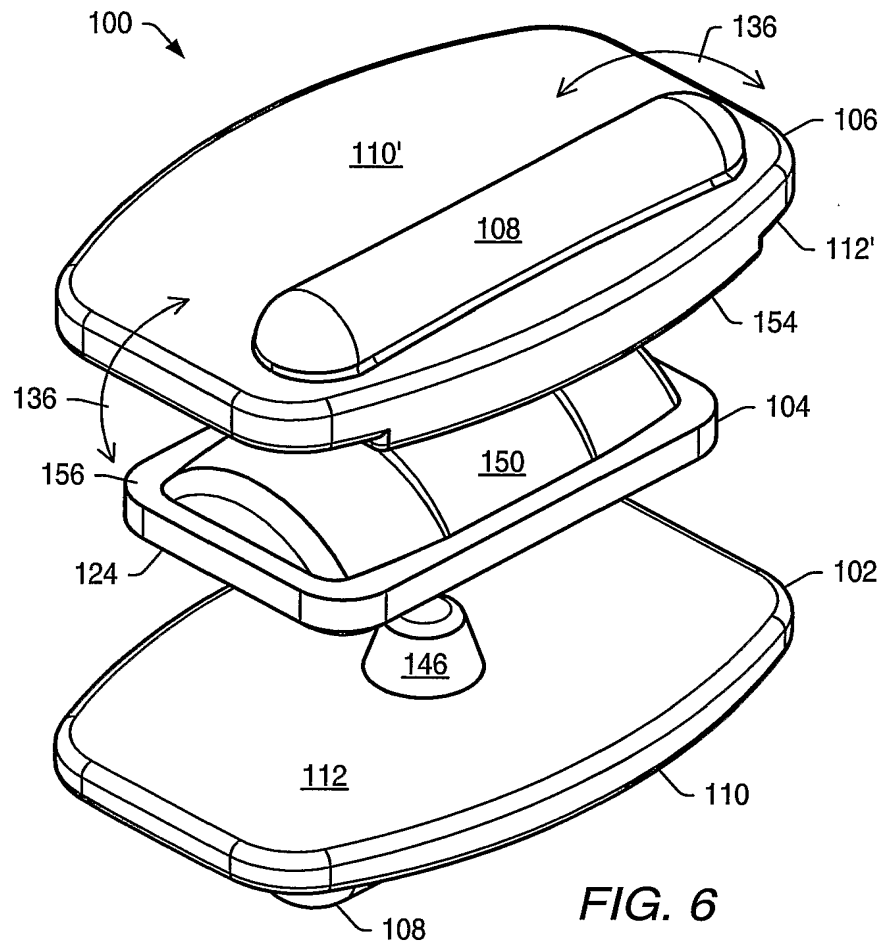


FIG. 3

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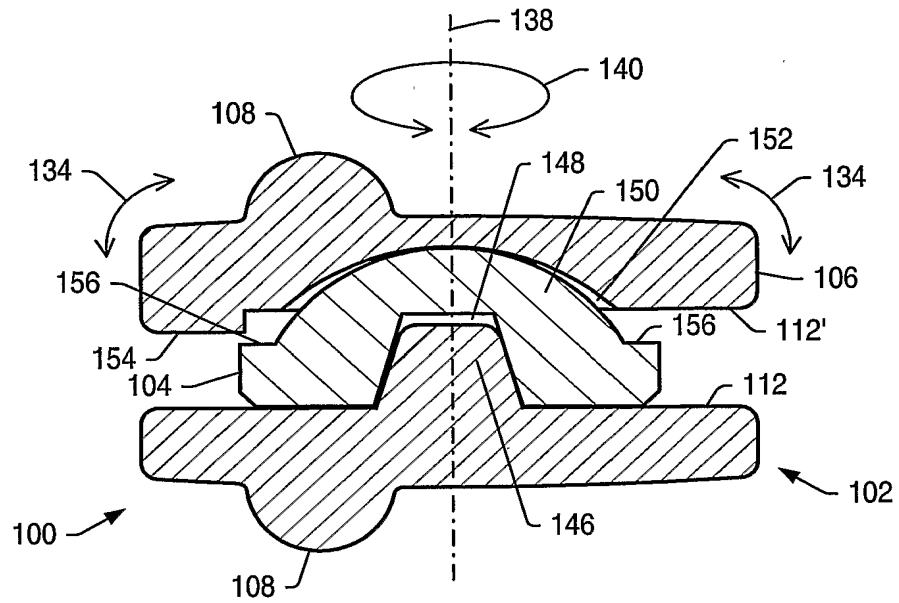


FIG. 7

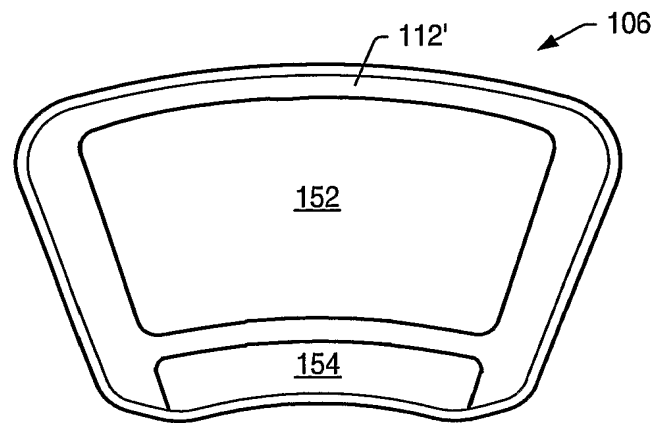


FIG. 8

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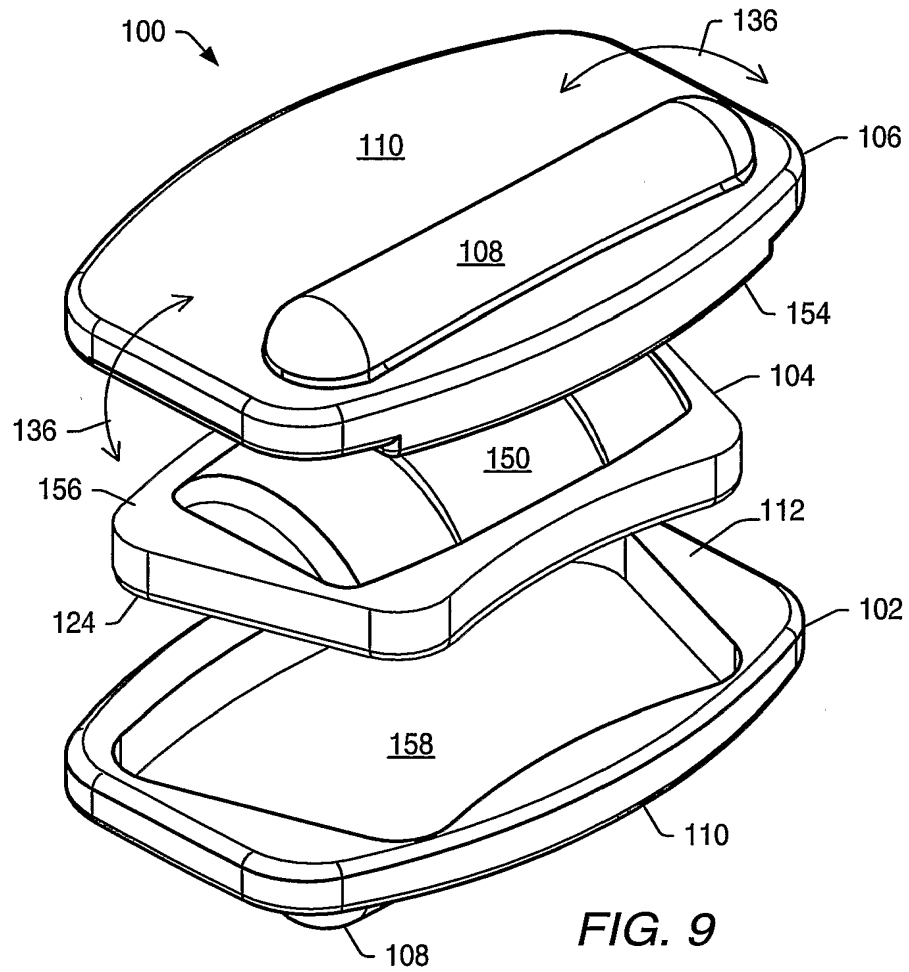


FIG. 9

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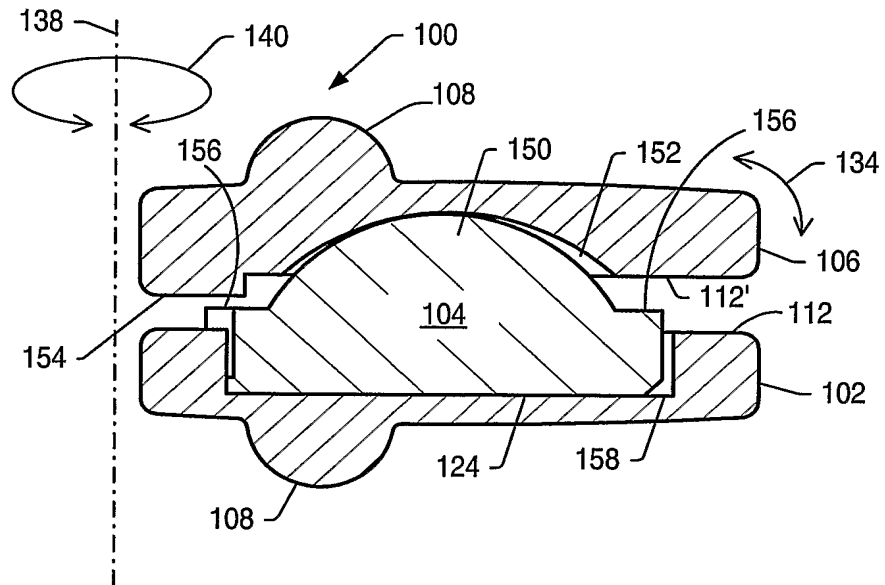


FIG. 10

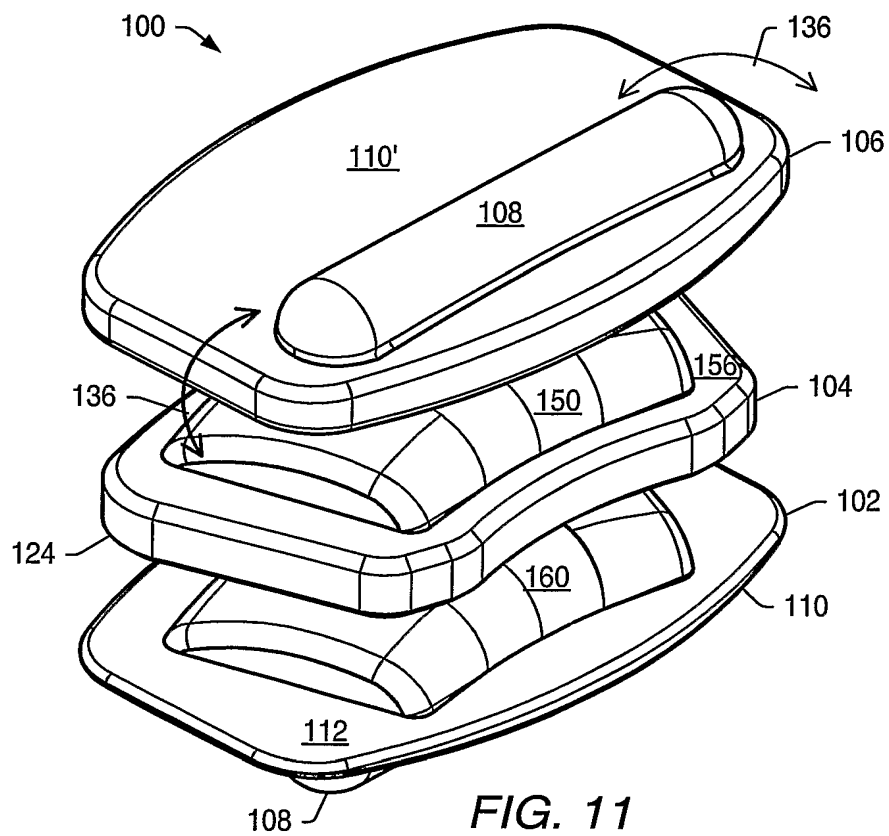


FIG. 11

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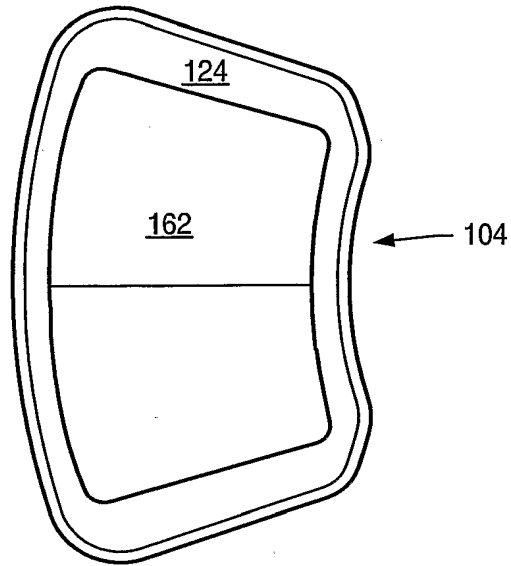


FIG. 12

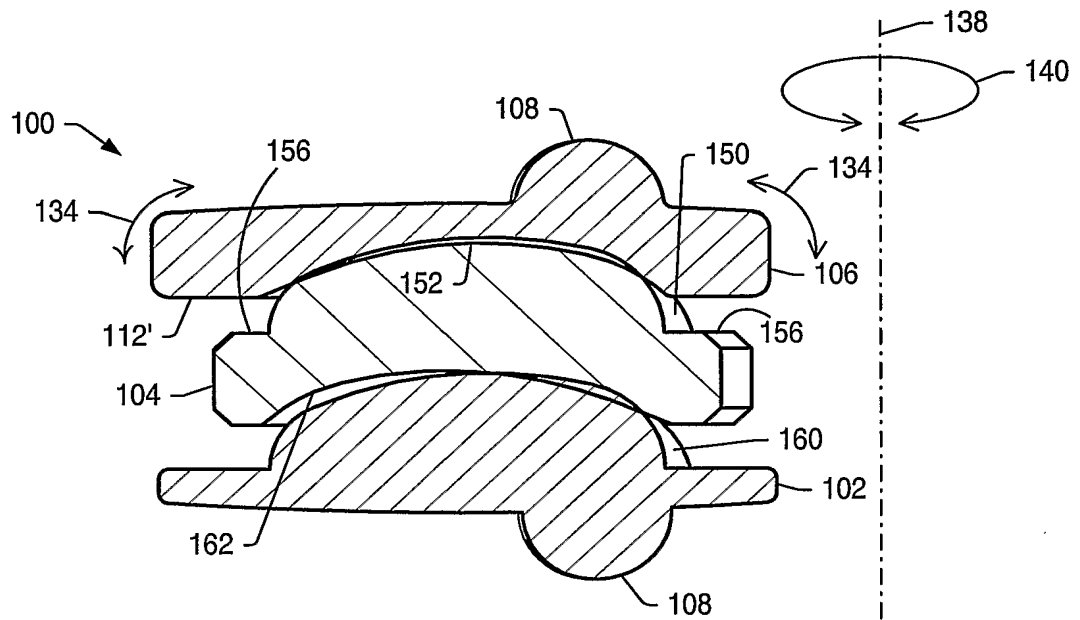


FIG. 13

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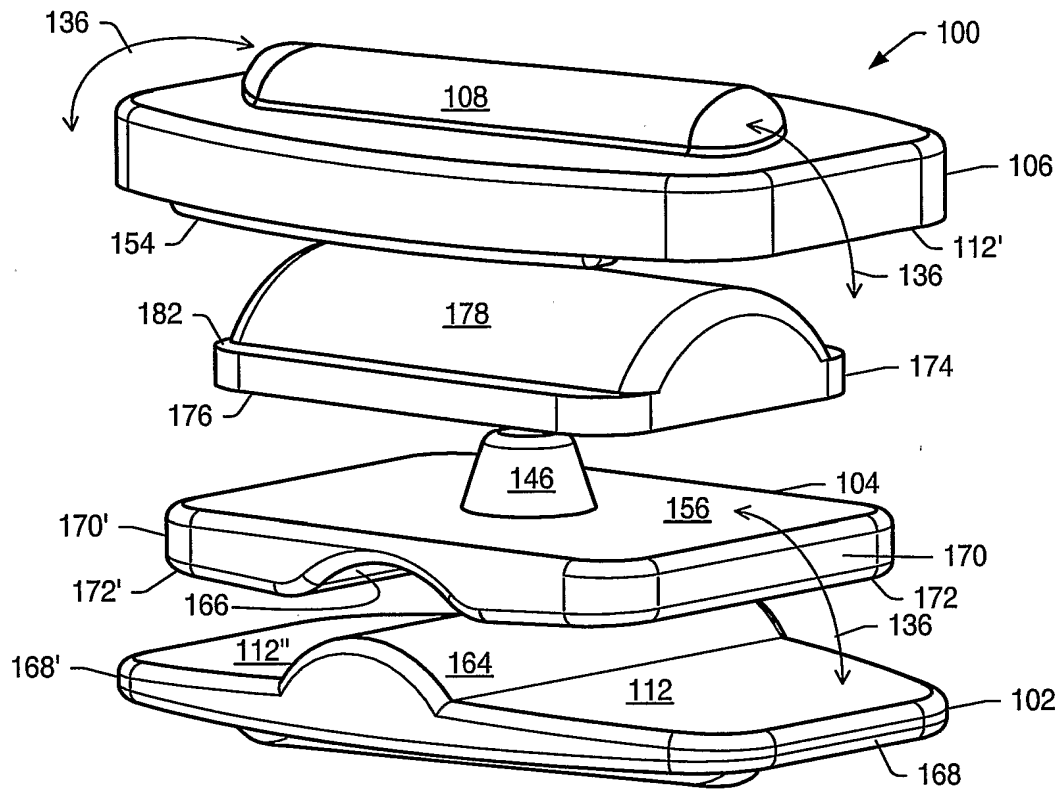


FIG. 14

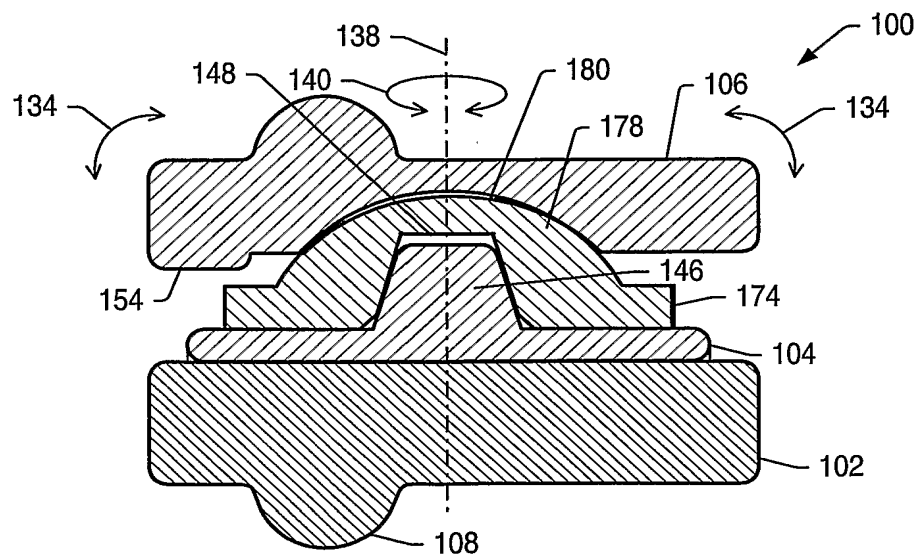


FIG. 15

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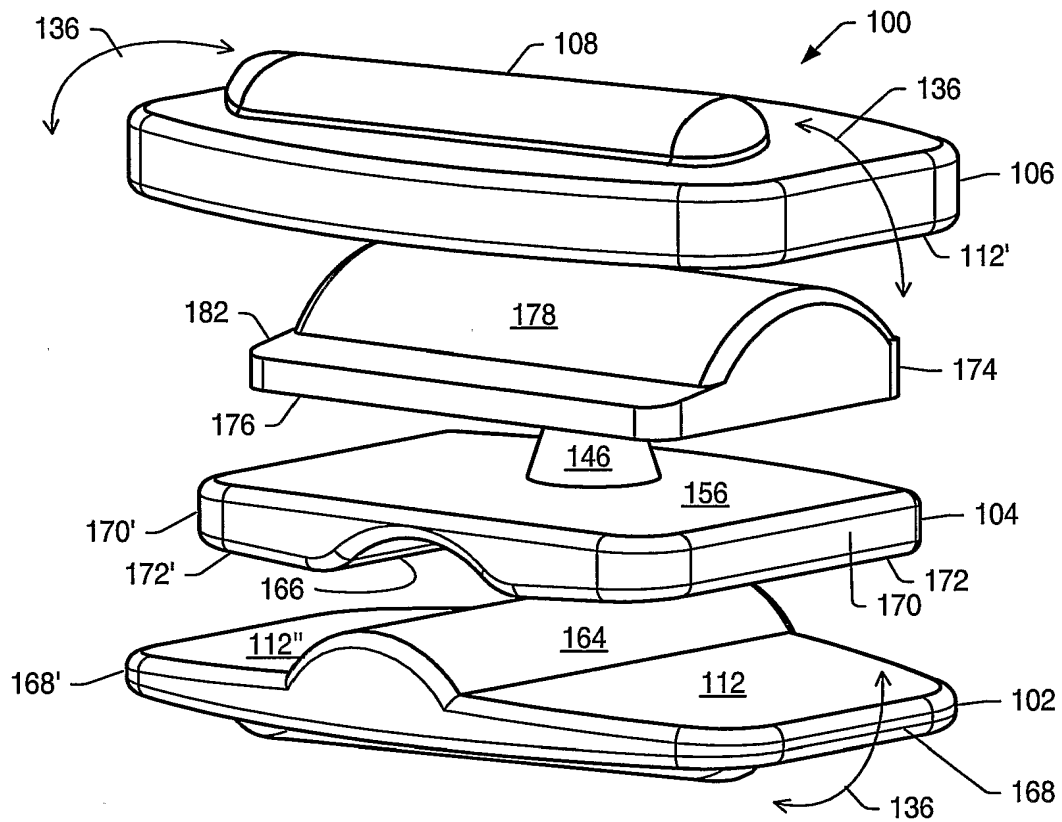


FIG. 16

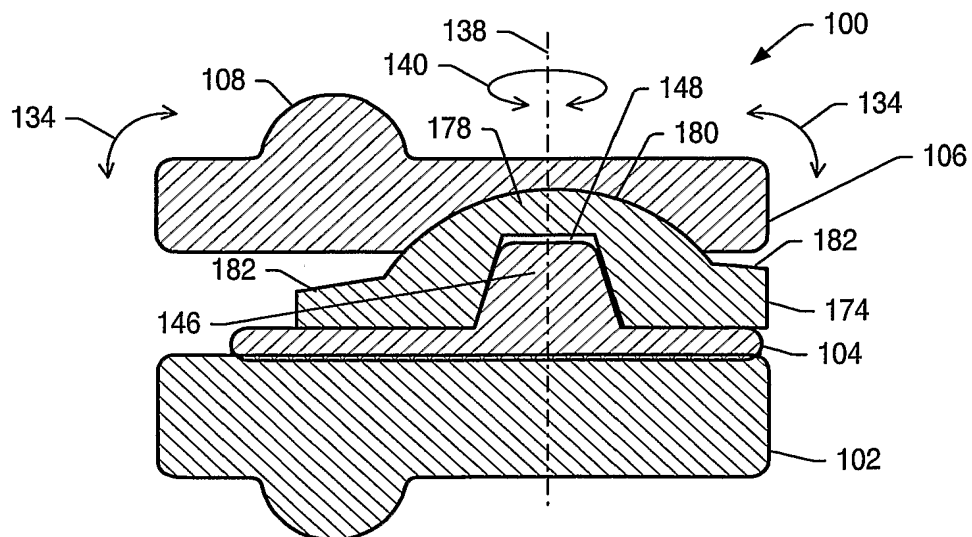


FIG. 17

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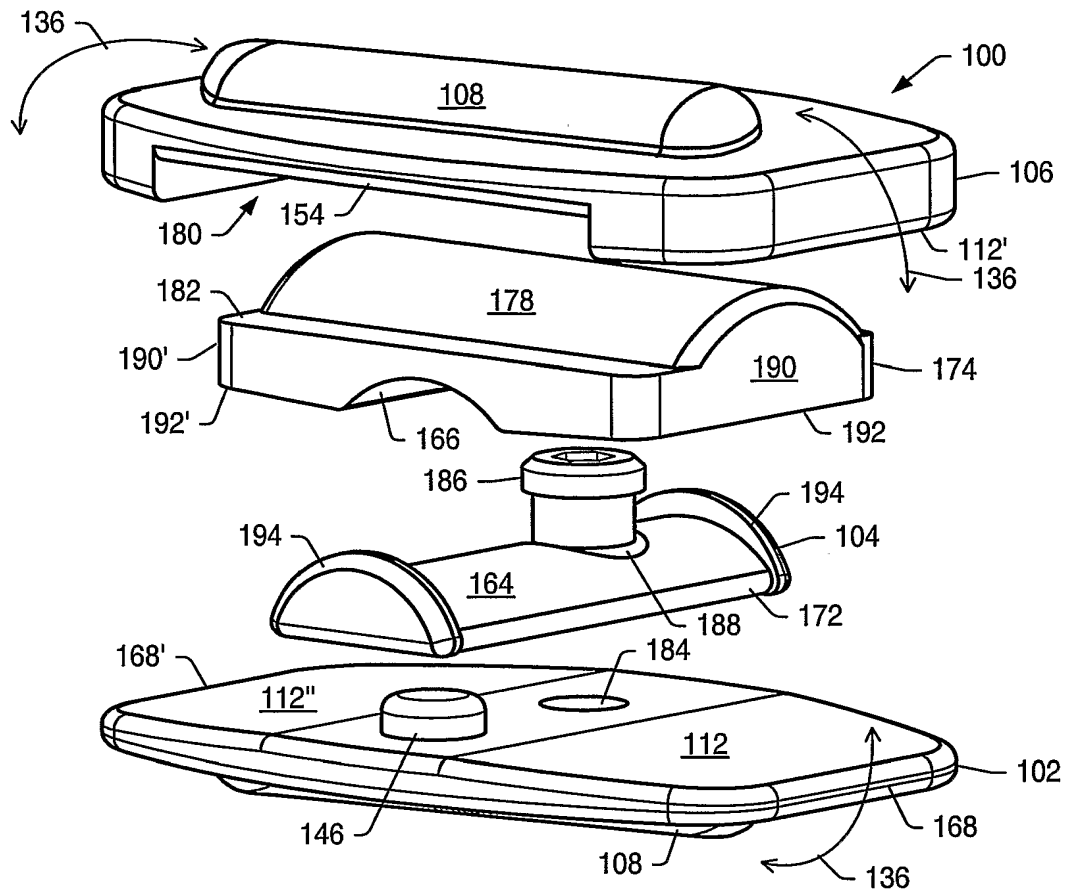


FIG. 18

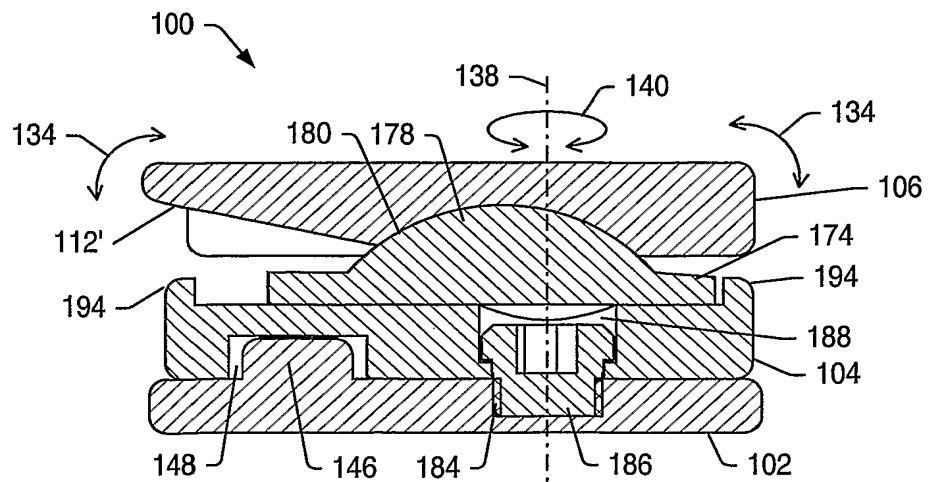


FIG. 19

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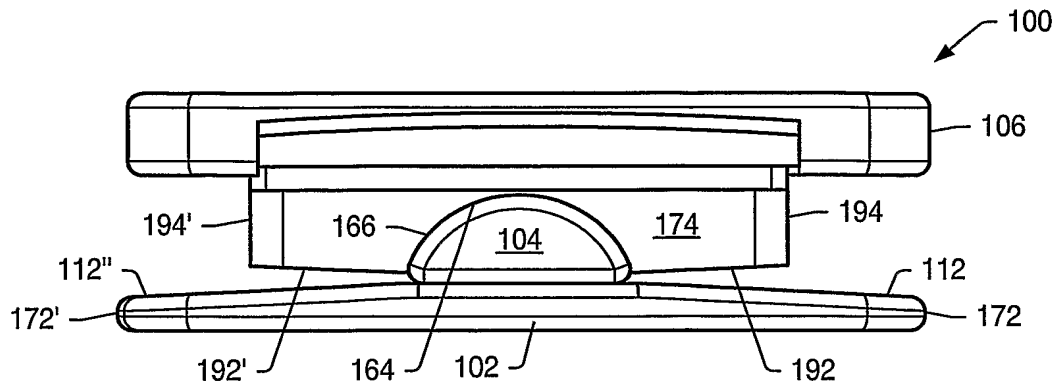


FIG. 20

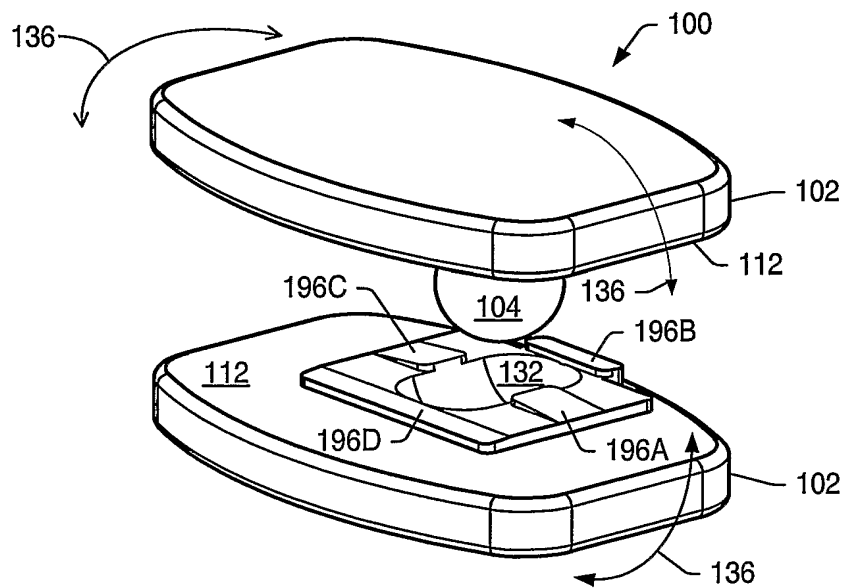


FIG. 21

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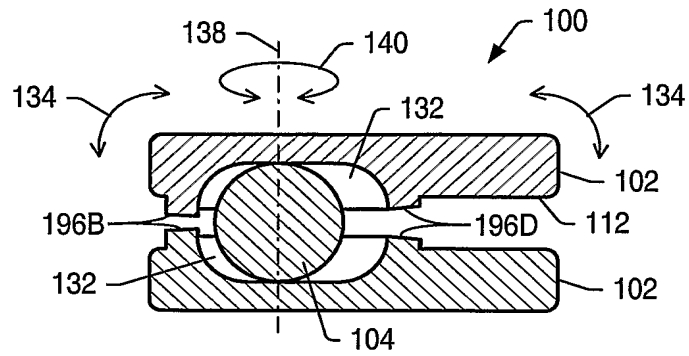


FIG. 22

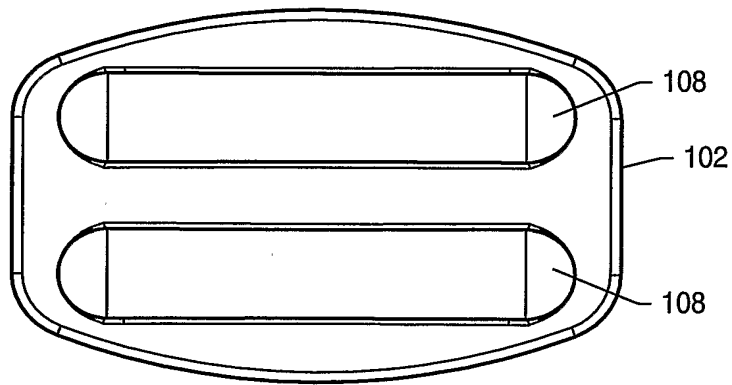


FIG. 23

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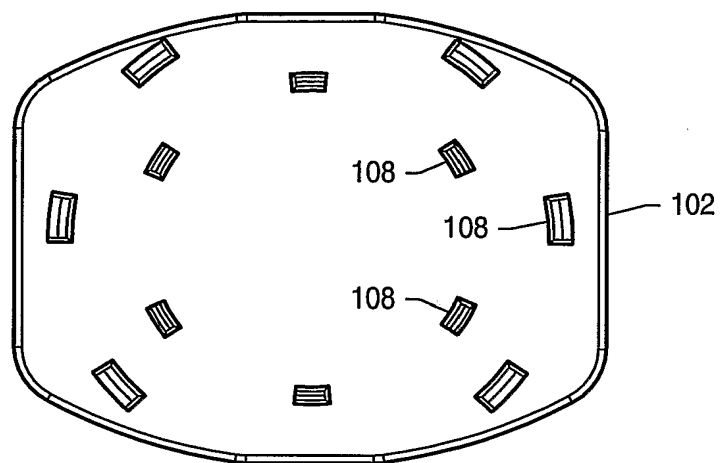


FIG. 24

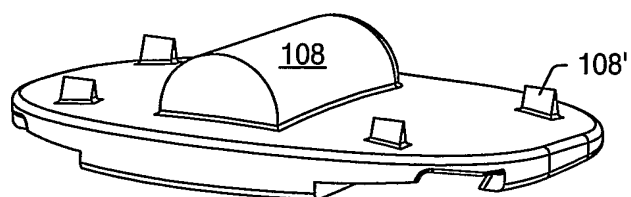


FIG. 25

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FIG. 26

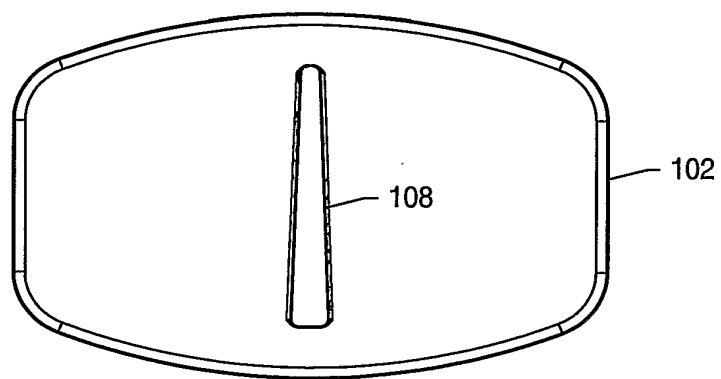
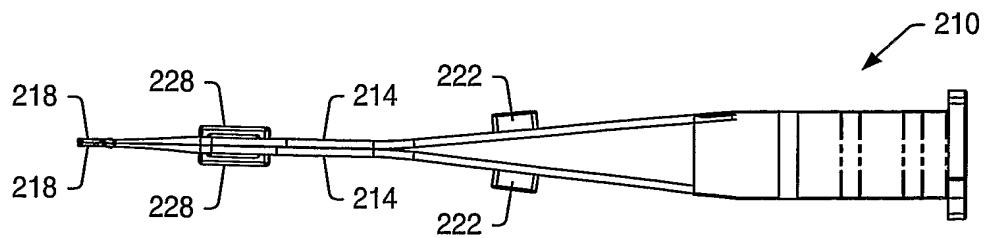
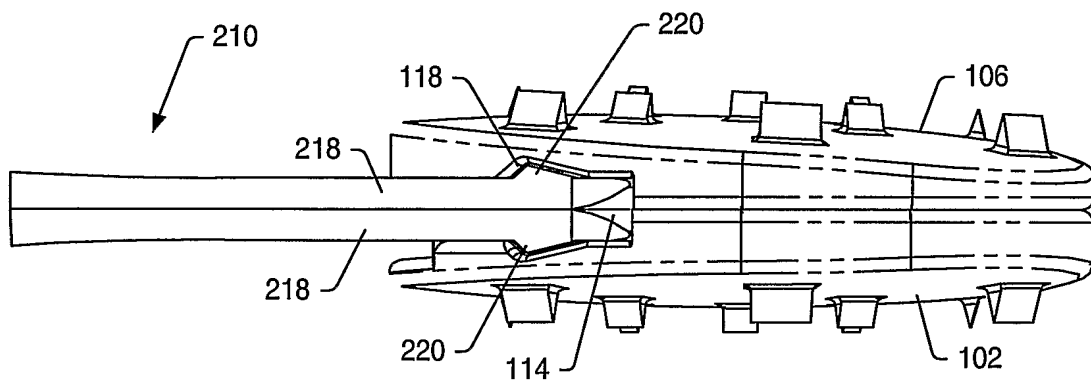
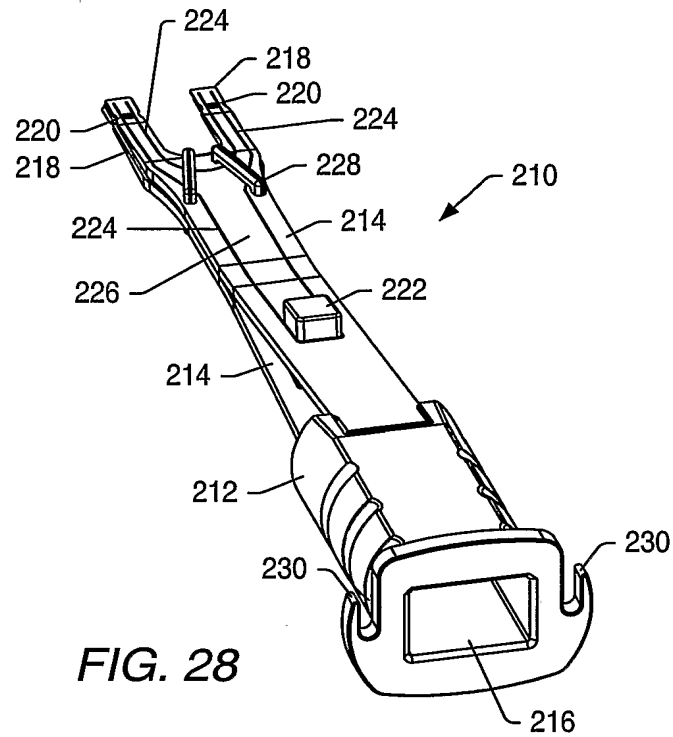


FIG. 27

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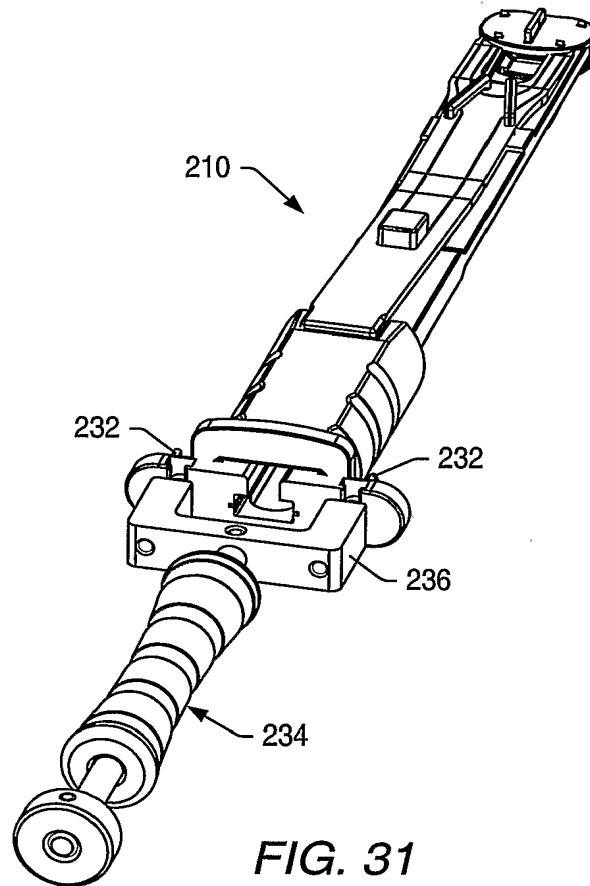


FIG. 31

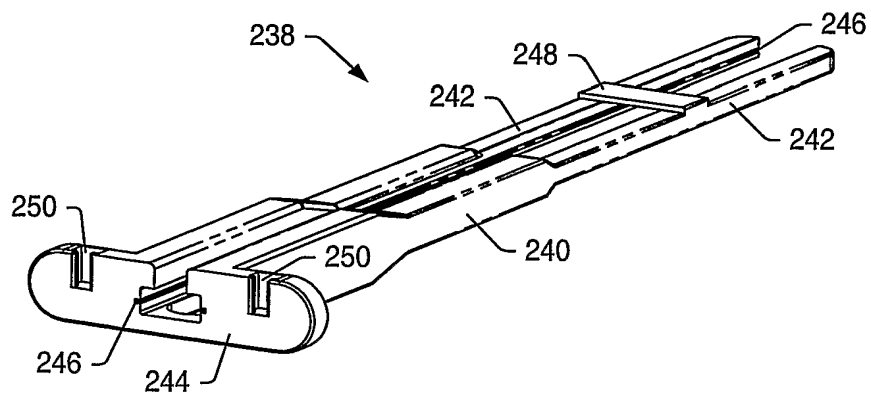
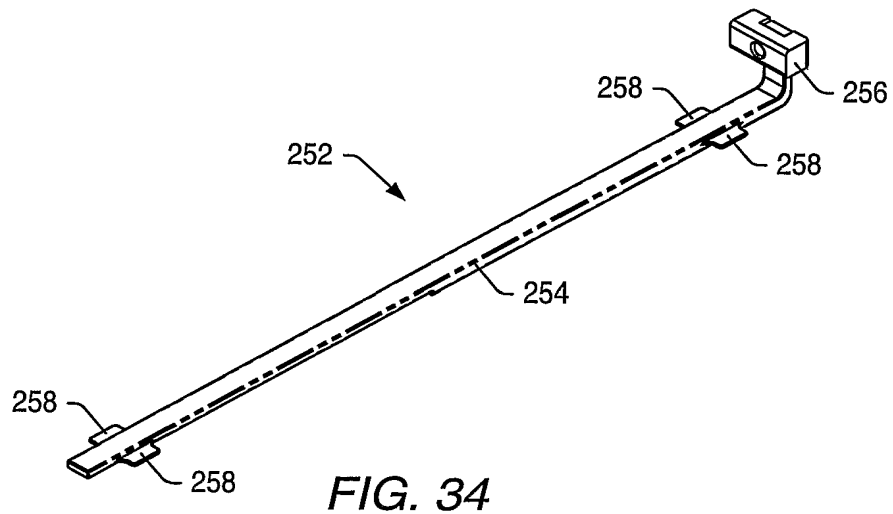
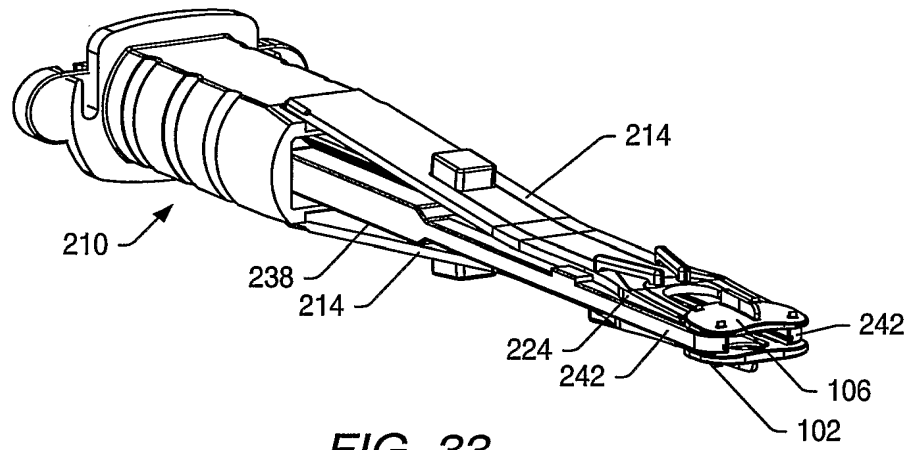
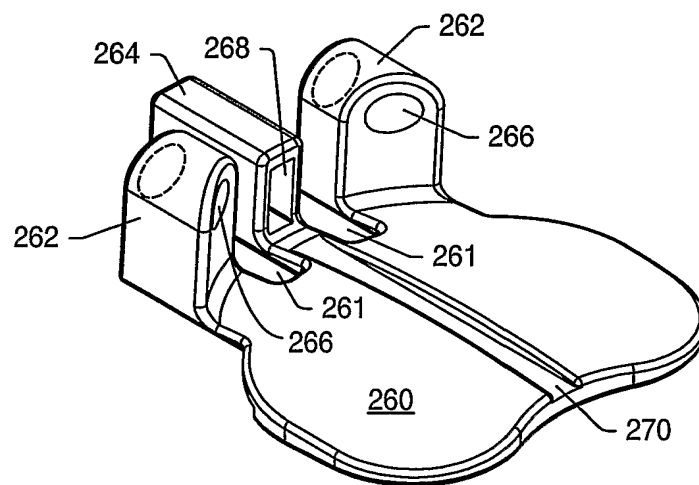
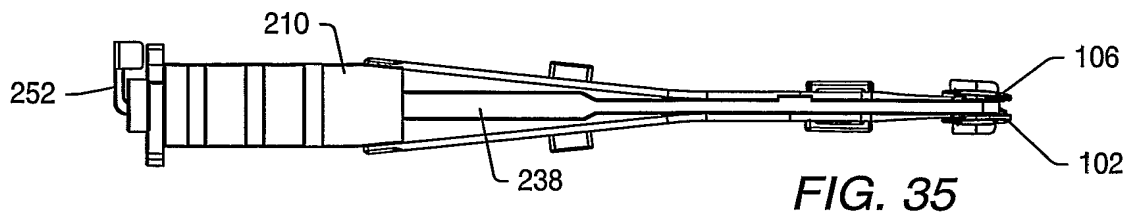


FIG. 32

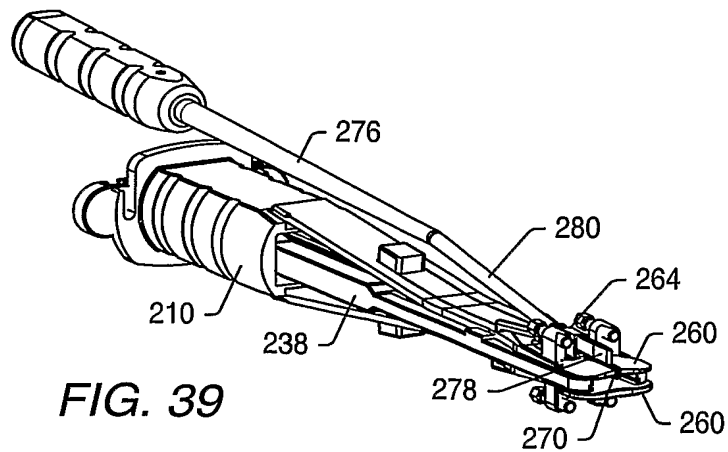
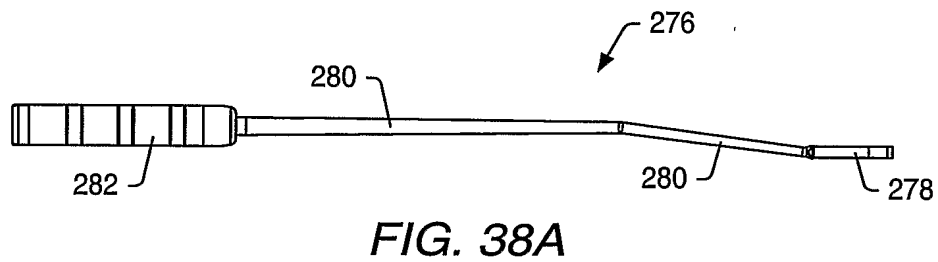
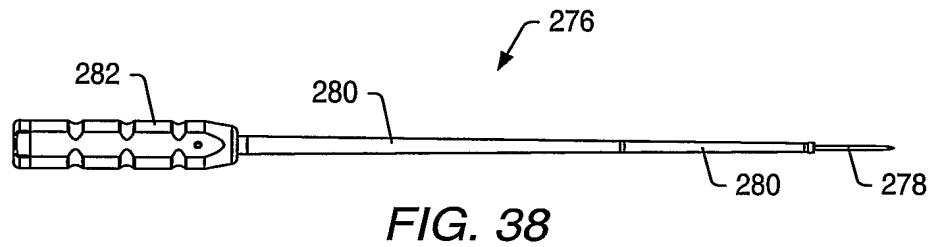
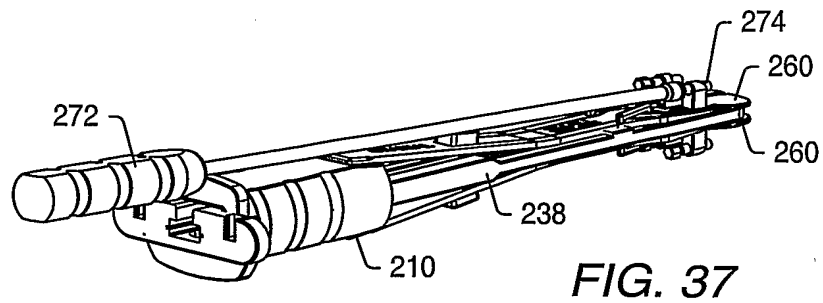
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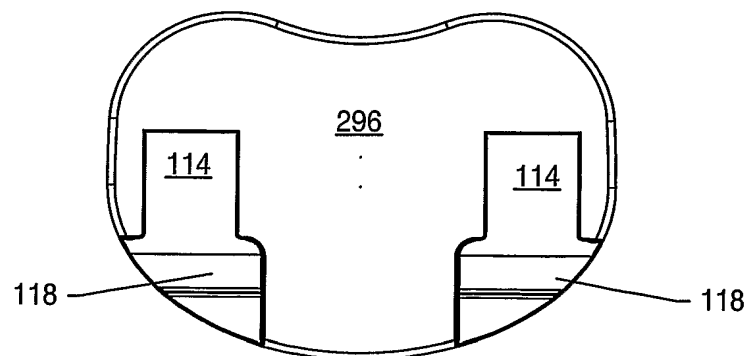
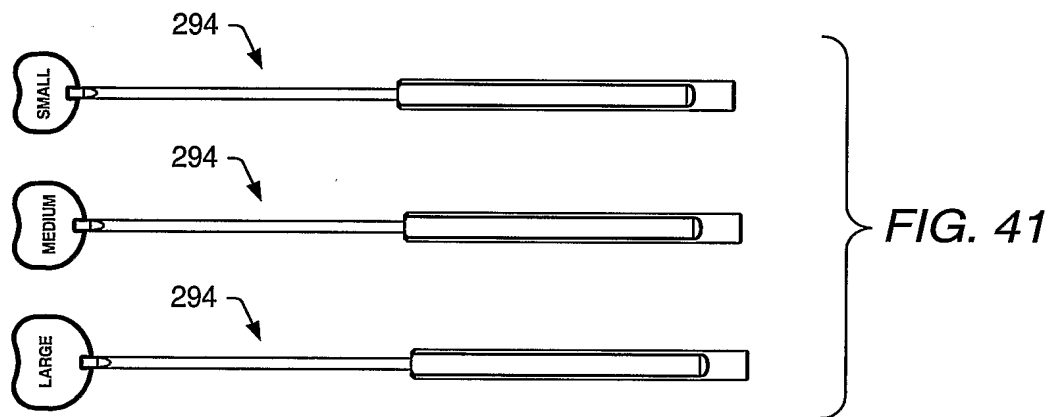
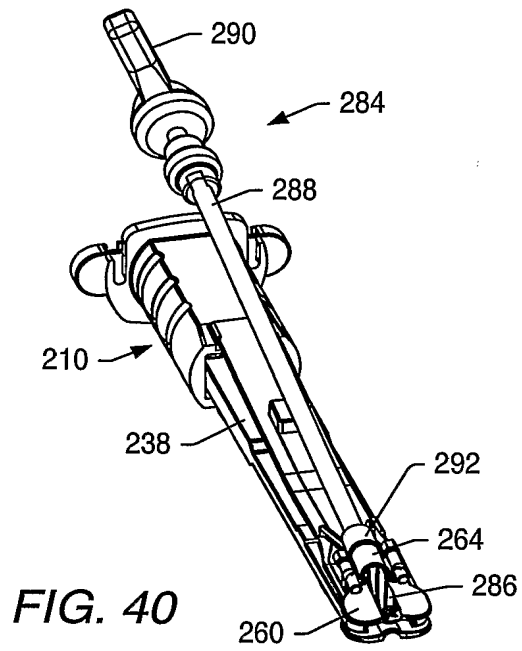
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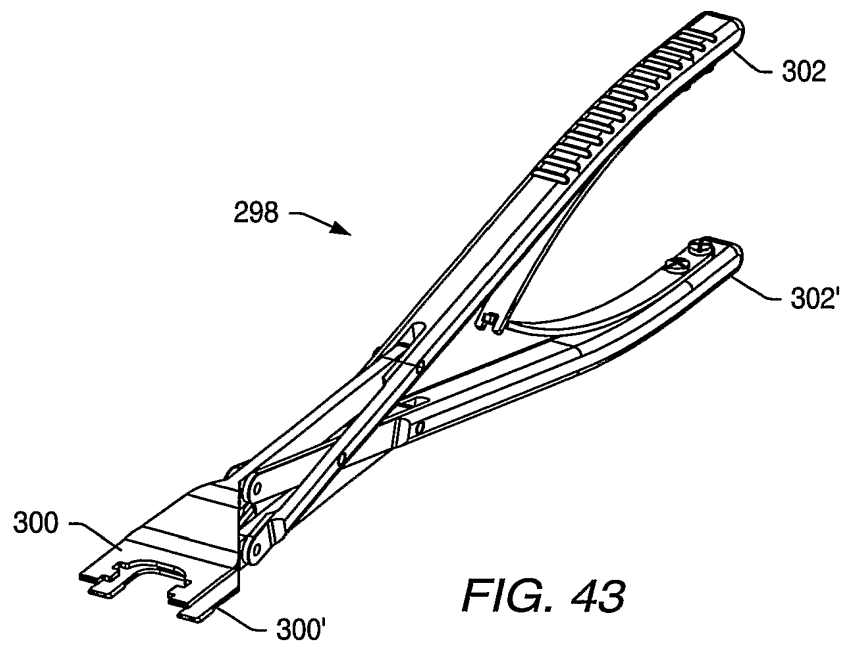
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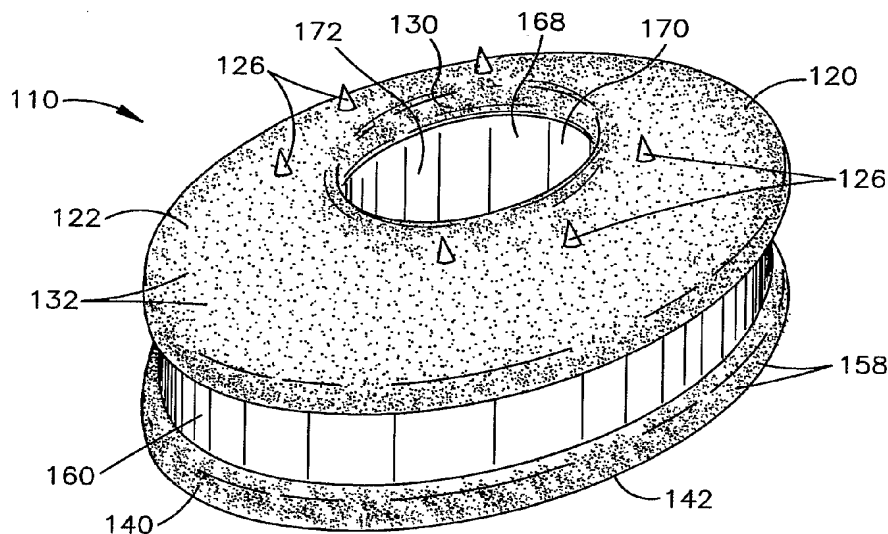
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(54) Title: ARTIFICIAL DISC



(57) **Abstract:** An artificial disc to replace a damaged spinal disc in a spinal column includes an upper retaining member having an outer surface engageable with a first vertebra of the spinal column and an inner surface. A lower retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface. A resilient core interconnects the upper and lower retaining members. The resilient core has an upper surface affixed to the inner surface of the upper retaining member. The resilient core has a lower surface affixed to the inner surface of the lower retaining member. The resilient core has a surface extending from one of the upper and lower surfaces toward another of the upper and lower surfaces and at least partially defining an empty space extending from the one of the upper and lower surfaces.

ARTIFICIAL DISC

Field of the Invention

The present invention relates to an artificial disc to replace a damaged spinal disc in a spinal column.

Background of the Invention

A known artificial disc is disclosed in U.S. Patent No. 5,893,889. U.S. Patent No. 5,893,889 discloses an artificial disc having upper and lower members for engaging adjacent vertebrae. A spherical pivot ball on a post extends upwardly from the lower member. The spherical pivot ball is received in a spherical pivot socket on the upper member. Between the upper and lower members and surrounding the post and pivot ball is an annular resilient cushion member.

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Summary of the Invention

An artificial disc to replace a damaged spinal disc in a spinal column includes an upper retaining member having an outer surface engageable with a first
5 vertebra of the spinal column and an inner surface. A lower retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface. A resilient core interconnects the upper and lower retaining members. The resilient core
10 has an upper surface affixed to the inner surface of the upper retaining member. The resilient core has a lower surface affixed to the inner surface of the lower retaining member. The resilient core has a surface extending from one of the upper and lower surfaces
15 toward another of the upper and lower surfaces and at least partially defining an empty space extending from the one of the upper and lower surfaces.

In one embodiment of an artificial disc constructed in accordance with the invention, the upper
20 and lower surfaces have recesses defining first and second empty spaces. In a second embodiment of the invention, the resilient core includes an opening extending from the upper surface to the lower surface to define the empty space.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent one skilled in the art to which the present invention relates upon
5 consideration of the following description of the invention with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial view of an artificial disc constructed in accordance with a first embodiment of
10 the present invention;

Fig. 2 is a schematic side view of the artificial disc of Fig. 1;

Fig. 3 is a sectional view of the artificial disc of Fig. 1;

15 Fig. 4 is a schematic sectional view of the artificial disc of Fig. 1 between adjacent vertebrae of a human spinal column;

Fig. 5 is a schematic sectional view of the artificial disc of Fig. 1 between adjacent vertebrae of
20 the spinal column showing the spinal column in flexion;

Fig. 6 is a pictorial view of an artificial disc constructed in accordance with a second embodiment of the present invention;

-4-

Fig. 7 is a schematic side view of the artificial disc of Fig. 6;

Fig. 8 is a sectional view of the artificial disc of Fig. 6;

5 Fig. 9 is a schematic sectional view of the artificial disc of Fig. 6 between adjacent vertebrae of a human spinal column; and

Fig. 10 is a schematic sectional view of the artificial disc of Fig. 6 between adjacent vertebrae of the spinal column showing the spinal column in flexion.

Description of the Invention

The present invention relates to an artificial disc to replace a damaged or degenerated spinal disc in a spinal column of a human. As representative of the present invention, Fig. 1 illustrates a first embodiment of an artificial disc 10. The artificial disc 10 (Fig. 4) is used to replace a damaged spinal disc between adjacent upper and lower vertebrae 12 and 14 of a human spinal column 16. The disc 10 has an oval-shaped outer periphery. It is contemplated that the outer periphery of the disc may have any desired shape.

The artificial disc 10 (Figs. 1-3) includes an upper retaining member 20, a lower retaining member 40,

-5-

and a resilient core 60 interconnecting the two retaining members. The retaining members 20 and 40 are only interconnected by the core 60. The upper and lower retaining members 20 and 40 are identical to each other and the disc 10 is symmetrical about a horizontally extending plane A (Figs. 2 and 3). The terms "upper" and "lower" are used herein with reference to the orientation of the disc 10 when it is implanted in the human body, as illustrated in Fig. 4, to distinguish the two identical retaining members for reference purposes.

The upper retaining member 20 is rigid and made of a biocompatible material such as a biocompatible metal or polymer. It is contemplated that the upper retaining member 20 could be made of a titanium alloy. The upper retaining member 20 (Figs. 1-4) has an outer convex surface 22 engageable with the vertebra 12. An inner concave surface 24 of the upper retaining ring 20 is affixed or bonded to the resilient core 60.

The upper retaining member 20 has an axially extending opening 30. The opening 30 extends through the outer surface 22 and the inner surface 24. The resilient core 60 may deflect into the opening 30 upon relative movement between the upper and lower retaining

-6-

members 20 and 40, such as when the spine 16 is bent in flexion, as shown in Fig. 5. The core 60 expends energy when the core deflects into the opening 30 to limit the amount of stress in the core. It is contemplated that the opening 130 may have any desired size and shape. It is also contemplated that the upper retaining member 20 may not include an opening 30.

Projections 26 extend from the outer surface 22 of the upper retaining member 20. The projections 26 (Figs. 4 and 5) engage the vertebra 12 to retain the disc 10 in position between the vertebrae 12 and 14. The outer surface 22 of the upper retaining member 20 also has beads 32 sintered on the outer surface to further retain the disc 10 between the vertebrae 12 and 14.

The lower retaining member 40 (Figs. 2-4) is identical in configuration to the upper retaining member 20. The lower retaining member 40 is rigid and made from the same material as the upper retaining member 20, such as a titanium alloy. The lower retaining member 40 has a convex outer surface 42 engageable with the vertebra 14. An inner concave surface 44 of the lower retaining member 40 is affixed or bonded to the resilient core 60.

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The lower retaining member 40 has an axially extending opening 50. The opening 50 extends through the outer surface 42 and the inner surface 44. The resilient core 60 may deflect into the opening 50 upon relative movement between the upper and lower retaining members 20 and 40, as shown in Fig. 5. The core 60 expends energy when the core deflects into the opening 50 to limit the amount of stress in the core. It is contemplated that the opening 50 may have any desired size and shape. It is also contemplated that the lower retaining member 40 may not include an opening 50.

Projections 56 extend from the outer surface 42 of the lower retaining member 40. The projections 56 (Figs. 4 and 5) engage the vertebra 14 to retain the disc 10 in position between the vertebrae 12 and 14. The outer surface 42 also has beads 58 sintered on the outer surface to further retain the disc 10 between the vertebrae 12 and 14.

The resilient core 60 is made of a urethane silicon blend and manufacturer by The Polymer Technology Group located in Berkley, California. The resilient core 60 may be adhered or bonded to the upper and lower retaining members 20 and 40 in any manner

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known in the art. It is contemplated that the resilient core 60 could be insert molded, transfer molded, or injection molded between the upper and lower retaining members 20 and 40. The core 60 may be molded
5 between the upper and lower retaining members 20 and 40 by injecting the material for the core through one of the openings 30 or 50 in the upper and lower retaining members. It is contemplated that the resilient core 60 may be wedge-shaped so that the upper retaining
10 member 20 is spaced from the lower retaining member 40 a first distance adjacent one side of the disc 10 and spaced from the lower retaining member 40 a second distance adjacent another side of the disc 10.

The core 60 has an upper convex surface 62. The
15 upper convex surface 62 is affixed to the concave inner surface 24 of the upper retaining member 20. A convex lower surface 64 of the core 60 is affixed to the concave inner surface 44 of the lower retaining member 40. The concave inner surfaces 24 and 44 limit
20 the amount of stress in the core 60 upon relative movement of the upper and lower retaining members 20 and 40.

The core 60 (Figs. 1-4) has a tapered or frustoconical surface 68 extending from the upper

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convex surface 62 toward the lower convex surface 64.
The surface 68 at least partially defines an empty
space 70 that extends from the upper convex surface 62
toward the lower convex surface 64. The surface 68
5 extends from the upper convex surface 62 to a
surface 72 that extends transverse to the axis 74 of
the disc 10 and generally parallel to the plane A. The
surfaces 68 and 70 define a concave recess 76 in the
upper surface that is coaxial with the disc 10 and
10 defines the empty space 70. The resilient core 60
deflects into the empty space 70 defined by the
recess 76 upon relative movement between the upper and
lower retaining members 20 and 40, as shown in Fig. 5.
The core 60 expends energy when the core deflects into
15 the empty space 70 to limit the amount of stress in the
core. It is contemplated that the recess 76 may have
any desired shape or depth and be in any desired
location in the upper surface 62. It is also
contemplated that the upper surface 62 may have any
20 number of recesses.

A tapered or frustoconical surface 80 extends from
the lower convex surface 64 of the core 60 toward the
upper convex surface 62. The surface 80 at least
partially defines an empty space 82 extending from the

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lower convex surface 64 toward the upper convex surface 62. The surface 80 extends from the lower surface 64 to a surface 84 extending transverse to the axis 74 and generally parallel to the plane A and the surface 72. The surfaces 80 and 84 define a concave recess 86 in the lower surface 64 that is coaxial with the disc 10 and defines the empty space 82. The resilient core 60 deflects into the empty space 82 upon relative movement between the upper and lower retaining members 20 and 40, as shown in Fig. 5. The core 60 expends energy when the core deflects into the empty space 82 to limit the amount of stress in the core. It is contemplated that the recess 86 may have any desired shape or depth and be in any desired location in the upper surface 62. It is also contemplated that the upper surface 62 may have any number of recesses.

When the disc 10 (Figs. 4 and 5) is in use in the spinal column 16, the upper retaining member 20 is affixed to the vertebra 12. The projections 26, the beads 32, and the convex surface 22 resist relative movement between the upper retaining member 20 and the vertebra 12. The lower retaining member 40 is affixed to the vertebra 14. The projections 56, the beads 58, and the convex surface 42 resist relative movement

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between the lower retaining member 40 and the
vertebra 14. When the upper retaining members 20
and 40 move relative to each other, such as when the
spine 16 is bent in flexion, as shown in Fig. 5, the
5 resilient core 60 deflects into the empty spaces 70
and 82 in the core. It is contemplated that the
core 60 may deflect into the openings 30 and 50 in the
retaining members 20 and 40. Accordingly, the core 60
expends energy to reduce stress in the core upon
10 relative movement of the upper and lower retaining
members 20 and 40 to provide a relatively long fatigue
life for the core 60.

An artificial disc 110 constructed in accordance
with a second embodiment of the present invention is
15 illustrated in Figs. 6-10. The artificial disc 110
(Fig. 9) is used to replace a damaged spinal disc
between adjacent upper and lower vertebrae 112 and 114
of a human spinal column 116. The disc 110 has an
oval-shaped outer periphery. It is contemplated that
20 the outer periphery of the disc may have any desired
shape.

The artificial disc 110 (Figs. 6-8) includes an
upper retaining member 120, a lower retaining
member 140, and a resilient core 160 interconnecting

-12-

the two retaining members. The retaining members 120 and 140 are only interconnected by the core 160. The upper and lower retaining members 120 and 140 are identical to each other and the disc 110 is symmetrical about a horizontally extending plane B (Figs. 7 and 8). The terms "upper" and "lower" are used herein with reference to the orientation of the disc 110 when it is implanted in the human body, as illustrated in Fig. 9, to distinguish the two identical retaining members for reference purposes.

The upper retaining member 120 is rigid and made of a biocompatible material such as a biocompatible metal or polymer. It is contemplated that the upper retaining member 120 could be made of a titanium alloy. The upper retaining member 120 (Figs. 6-9) has an outer convex surface 122 engageable with the vertebra 112. An inner concave surface 124 of the upper retaining member 120 is affixed or bonded to the resilient core 160.

The upper retaining member 120 has an axially extending opening 130. The opening 130 extends through the outer surface 122 and the inner surface 124. The resilient core 160 may deflect into the opening 130 upon relative movement between the upper and lower

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retaining members 120 and 140, such as when the spine 116 is bent in flexion. The core 160 expends energy when the core deflects into the opening 130 to limit the amount of stress in the core. It is contemplated that the opening 130 may have any desired size and shape. It is also contemplated that the upper retaining member 120 may not include an opening 130.

Projections 126 extend from the outer surface 122 of the upper retaining member 120. The projections 126 (Figs. 9 and 10) engage the vertebra 112 to retain the disc 110 in position between the vertebrae 112 and 114. The outer surface 122 of the upper retaining member 120 also has beads 132 sintered on the outer surface to further retain the disc 110 between the vertebrae 112 and 114.

The lower retaining member 140 (Figs. 7-9) is identical in configuration to the upper retaining member 120. The lower retaining member 140 is rigid and made from the same material as the upper retaining member 120, such as a titanium alloy. The lower retaining member 140 has a convex outer surface 142 engageable with the vertebra 114. An inner concave surface 144 of the lower retaining member 140 is affixed or bonded to the resilient core 160. The lower

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retaining member 140 has an axially extending opening 150. The opening 150 extends through the outer surface 142 and the inner surface 144. The resilient core 160 may deflect into the opening 150 upon relative movement between the upper and lower retaining members 120 and 140. The core 160 expends energy when the core deflects into the opening 150 to limit the amount of stress in the core. It is contemplated that the opening 150 may have any desired size and shape. It is also contemplated that the lower retaining member 140 may not include an opening 150.

Projections 156 extend from the outer surface 142 of the lower retaining member 140. The projections 156 (Figs. 9 and 10) engage the vertebra 114 to retain the disc 110 in position between the vertebrae 112 and 114. The outer surface 142 also has beads 158 sintered on the outer surface to further retain the disc 110 between the vertebrae 112 and 114.

The resilient core 160 is made of a urethane silicon blend and manufactured by The Polymer Technology Group located in Berkley, California. The resilient core 160 may be adhered or bonded to the upper and lower retaining members 120 and 140 in any manner known in the art. It is contemplated that the

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resilient core 160 could be insert molded, transfer molded, or injection molded between the upper and lower retaining members 120 and 140. The resilient core 160 may be molded between the upper and lower retaining members 120 and 140 by injecting the material for the core through one of the openings 130 or 150 in the upper and lower retaining members. It is contemplated that the resilient core 160 could be wedged-shaped so that the upper retaining member 120 may be spaced from the lower retaining member 140 a first distance adjacent one side of the disc 110 and spaced from the lower retaining member a second distance adjacent another side of the disc 110.

The resilient core 160 has an upper convex surface 162. The upper convex surface 162 is bonded to the concave inner surface 124 of the upper retaining member 120. A convex lower surface 164 of the resilient core 160 is bonded to the concave inner surface 144 of the lower retaining member 140. The concave inner surfaces 124 and 144 limit the amount of stress in the core 160 upon relative movement between the upper and lower retaining members 120 and 140.

The resilient core 160 has a cylindrical surface 168 extending from the upper surface 162 to the

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lower surface 164. The cylindrical surface 168 defines an empty space 170 in the core 160 extending from the upper surface 162 to the lower surface 164. The cylindrical surface 168 is coaxial with an axis 174 of the disc 110. The resilient core 160 deflects into the empty space 170 upon relative movement between the upper and lower retaining members 120 and 140, as shown in Fig. 10. The core 160 expends energy when the core deflects into the empty space 170 to limit the amount of stress in the core. It is contemplated that the opening 172 may have any desired shape and be in any desired location in the core 160. It is also contemplated that the core 160 may have any number of openings extending from the upper surface 162 to the lower surface 164.

When the disc 110 (Figs. 9 and 10) is in use in the spinal column 116, the upper retaining member 120 is affixed to the vertebra 112. The projections 126, the beads 132, and the convex surface 122 resist relative movement between the upper retaining member 120 and the vertebra 112. The lower retaining member 140 is affixed to the vertebra 114. The projections 156, the beads 158, and the convex surface 142 resist relative movement between the lower

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retaining member 140 and the vertebra 114. When the upper and lower retaining members 120 and 140 move relative to each other, such as when the spine 116 is bent in flexion, as shown in Fig. 10, the resilient core 160 deflects into the empty space 170 in the core. Accordingly, the core 160 expends energy to reduce stress in the core upon relative movement between the upper and lower retaining members 120 and 140 to provide a relatively long fatigue life for the core 160.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

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Having described the invention, the following is claimed:

1. An artificial disc to replace a damaged spinal disc in a spinal column, said artificial disc comprising:

an upper retaining member having an outer surface engageable with a first vertebra of the spinal column and an inner surface;

a lower retaining member having an outer surface engageable with a second vertebra of the spinal column and an inner surface; and

a resilient core interconnecting said upper and lower retaining members, said resilient core having an upper surface affixed to said inner surface of said upper retaining member, said resilient core having a lower surface affixed to said inner surface of said lower retaining member, said resilient core having a surface extending from one of said upper and lower surfaces toward another of said upper and lower surfaces and at least partially defining an empty space extending from said one of said upper and lower surfaces.

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2. An artificial disc as defined in claim 1 wherein one of said upper and lower surfaces includes a recess defining said empty space.

3. An artificial disc as defined in claim 2 wherein said surface extending from said one of said upper and lower surfaces extends to a second surface extending transverse to an axis of said disc to define said recess.

4. An artificial disc as defined in claim 3 wherein said surface extending from one of said upper and lower surfaces of said resilient core extends from said upper surface to said second surface to define said recess.

5. An artificial disc as defined in claim 2 wherein said recess is coaxial with said disc.

6. An artificial disc as defined in claim 1 wherein said surface extends from said upper surface of said resilient core toward said lower surface to at least partially define a first empty space extending from said upper surface toward said lower surface, said

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resilient core having a second surface extending from said lower surface toward said upper surface to at least partially define a second empty space extending from said lower surface toward said upper surface.

7. An artificial disc as defined in claim 6 wherein said upper surface of said resilient core has a first recess defining said first empty space and said lower surface of said resilient core has a second recess defining said second empty space.

8. An artificial disc as defined in claim 7 wherein said resilient core includes third and fourth surfaces extending transverse to an axis of said disc, said first surface extending from said upper surface to said third surface to define said first recess and said second surface extending from said lower surface to said fourth surface to define said second recess.

9. An artificial disc as defined in claim 8 wherein said third and fourth surfaces extend generally parallel to each other.

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10. An artificial disc as defined in claim 8 wherein said first and second recesses are coaxial with said disc.

11. An artificial disc as defined in claim 1 wherein said resilient core includes an opening extending from said upper surface to said lower surface to define said empty space.

12. An artificial disc as defined in claim 11 wherein said surface is cylindrical and extends from said upper surface of said core to said lower surface of said core to define said opening.

13. An artificial disc as defined in claim 12 wherein said cylindrical surface is coaxial with said disc.

14. An artificial disc as defined in claim 1 wherein said upper and lower retaining members are interconnected only by said core.

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15. An artificial disc as defined in claim 1 wherein one of said upper and lower retaining members has an opening extending through said inner and outer surfaces of said one of said upper and lower retaining members.

16. An artificial disc as defined in claim 15 wherein said opening extending through said inner and outer surfaces of said one of said upper and lower retaining members is axially aligned with said empty space.

17. An artificial disc as defined in claim 15 wherein said upper retaining member has an opening extending through said inner and outer surfaces of said upper retaining member, said lower retaining member having an opening extending through said inner and outer surfaces of said lower retaining member.

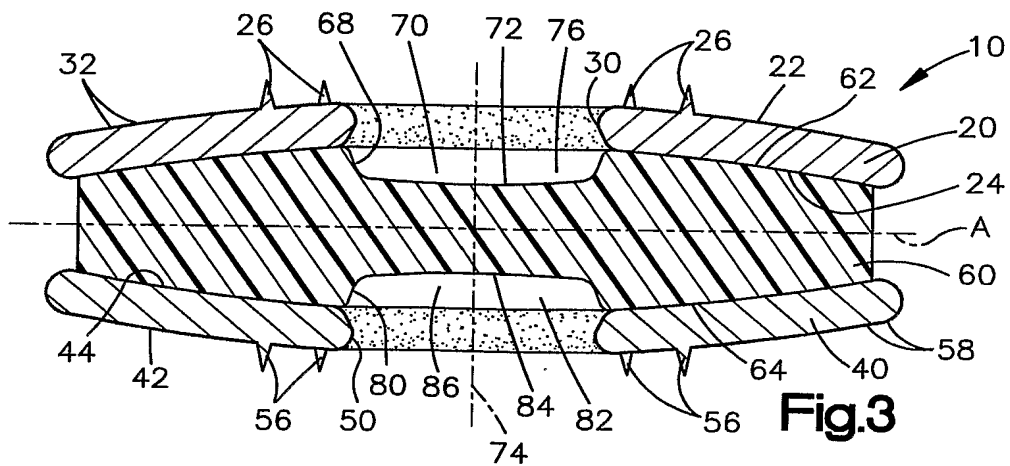
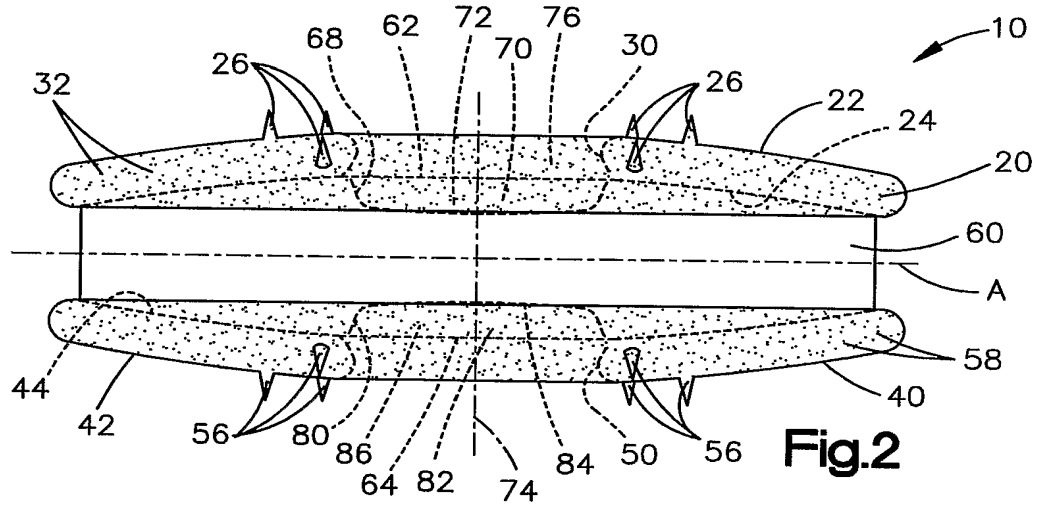
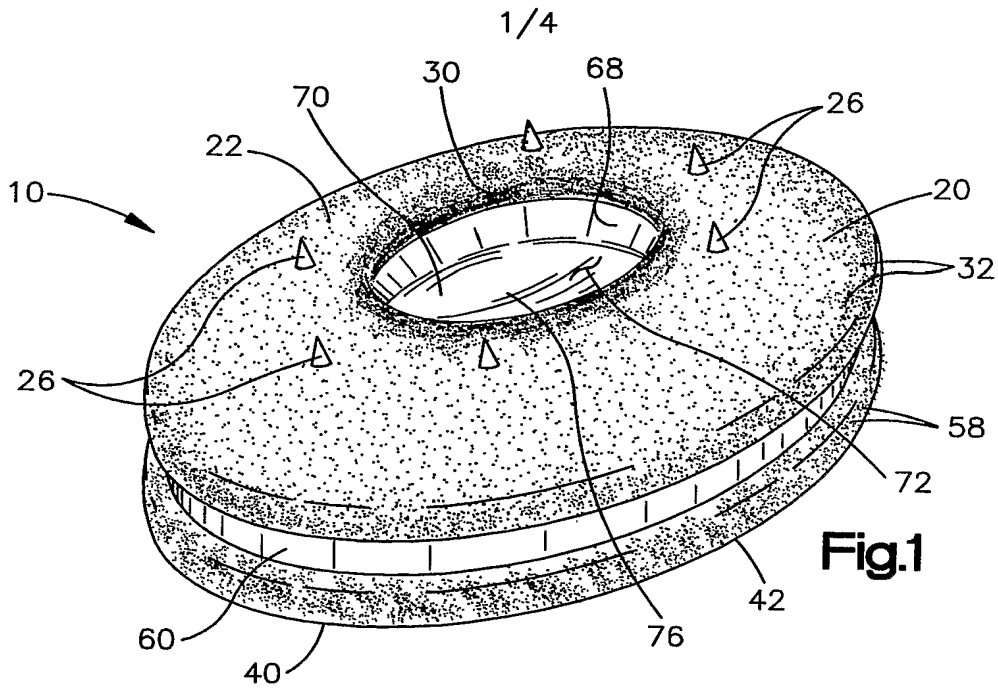
18. An artificial disc as defined in claim 15 wherein said opening extends axially through said one of said upper and lower retaining members.

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19. An artificial disc as defined in claim 1 wherein said upper and lower surfaces of said resilient core are convex and said inner surfaces of said upper and lower retaining members are concave.

20. An artificial disc as defined in claim 1 wherein said outer surfaces of said upper and lower retaining members are convex.

21. An artificial disc as defined in claim 20 wherein said inner surfaces of said upper and lower retaining members are concave, said upper and lower surfaces of said resilient core being convex.



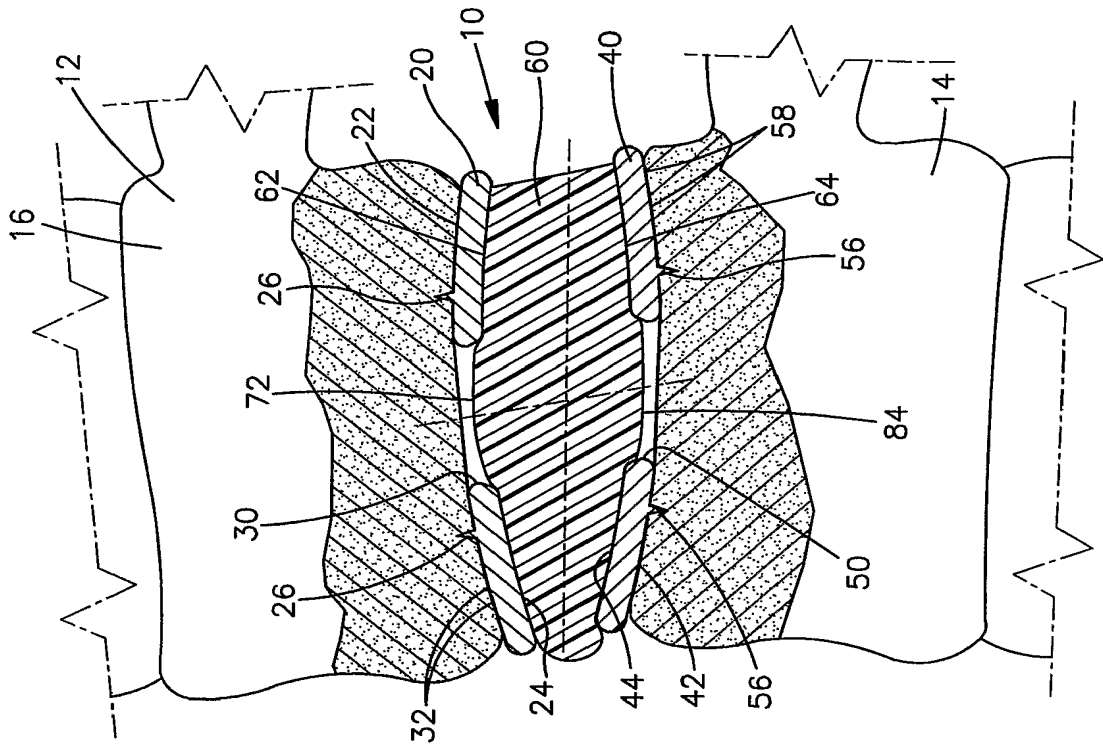


Fig.5

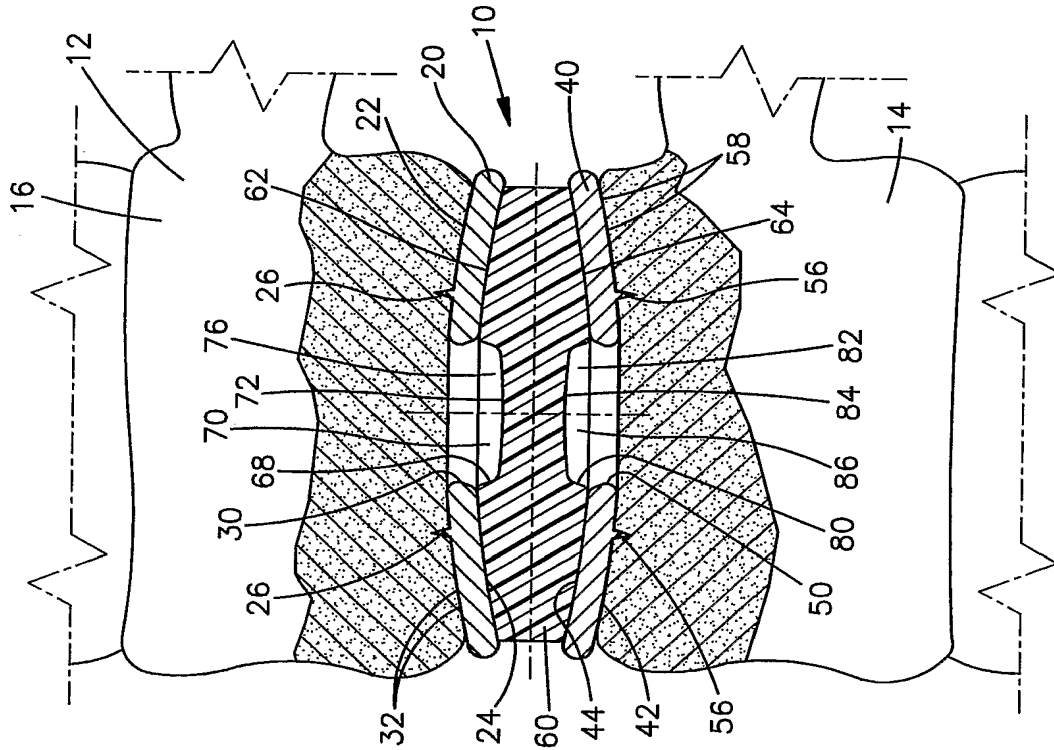


Fig.4

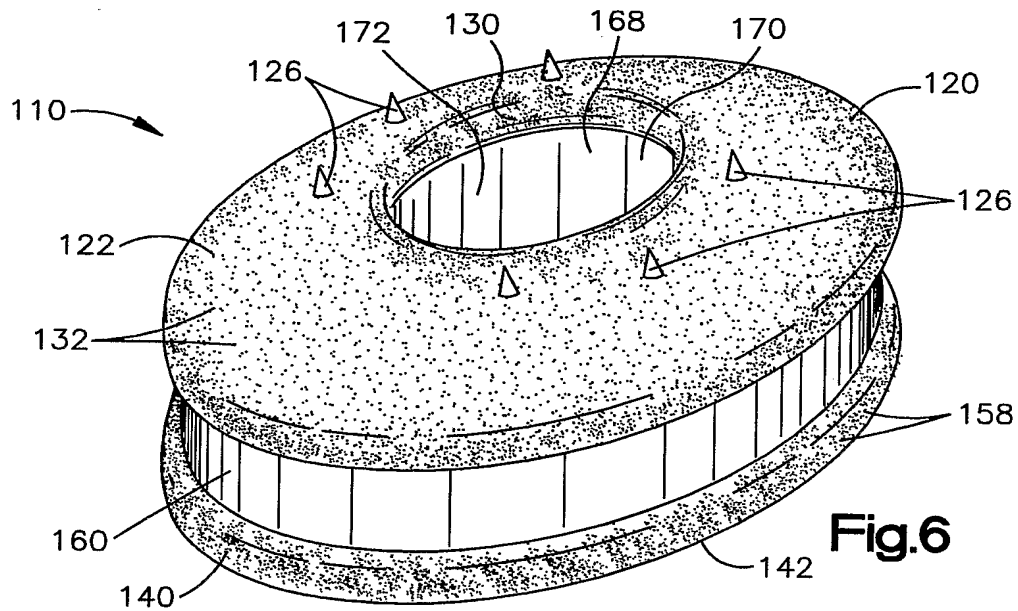


Fig.6

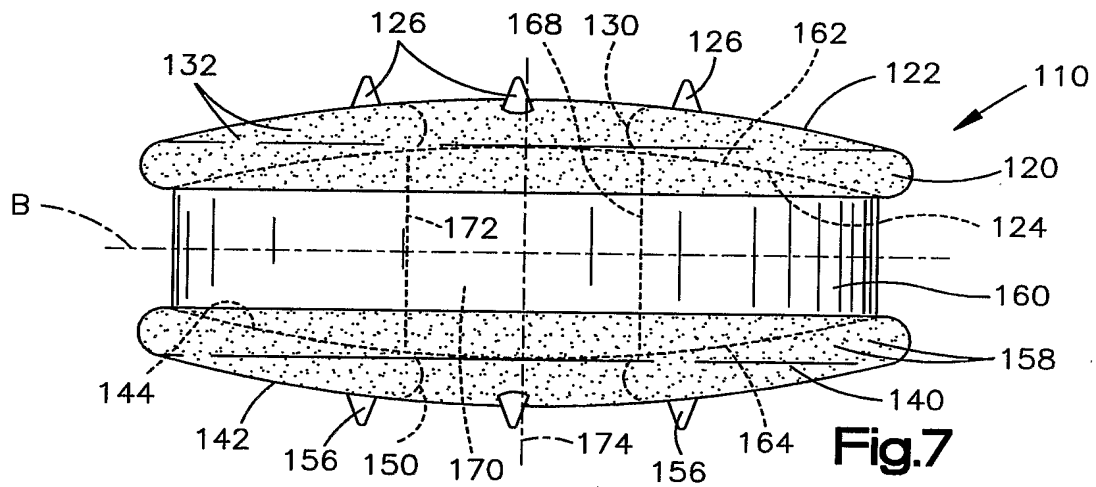


Fig.7

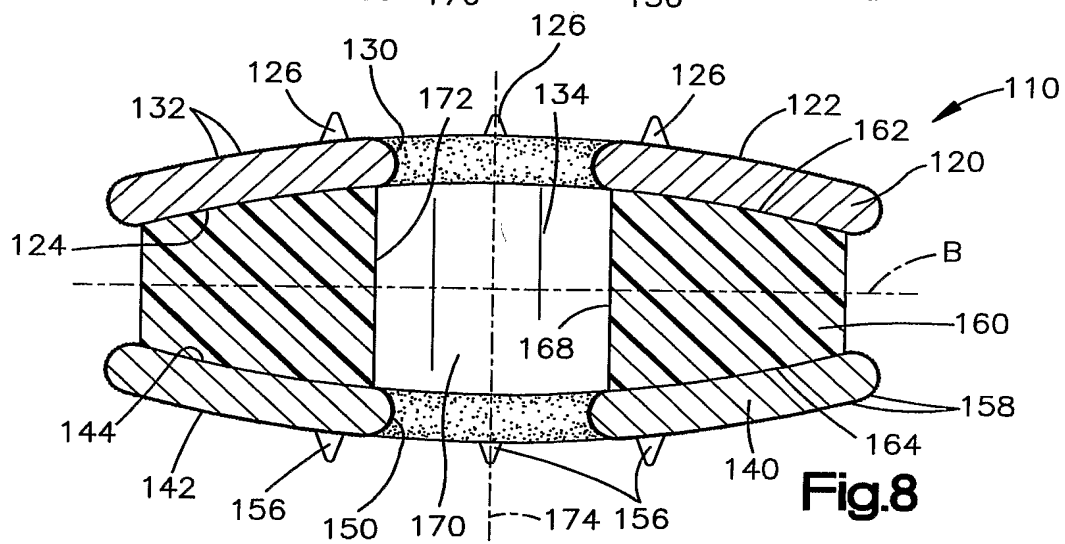
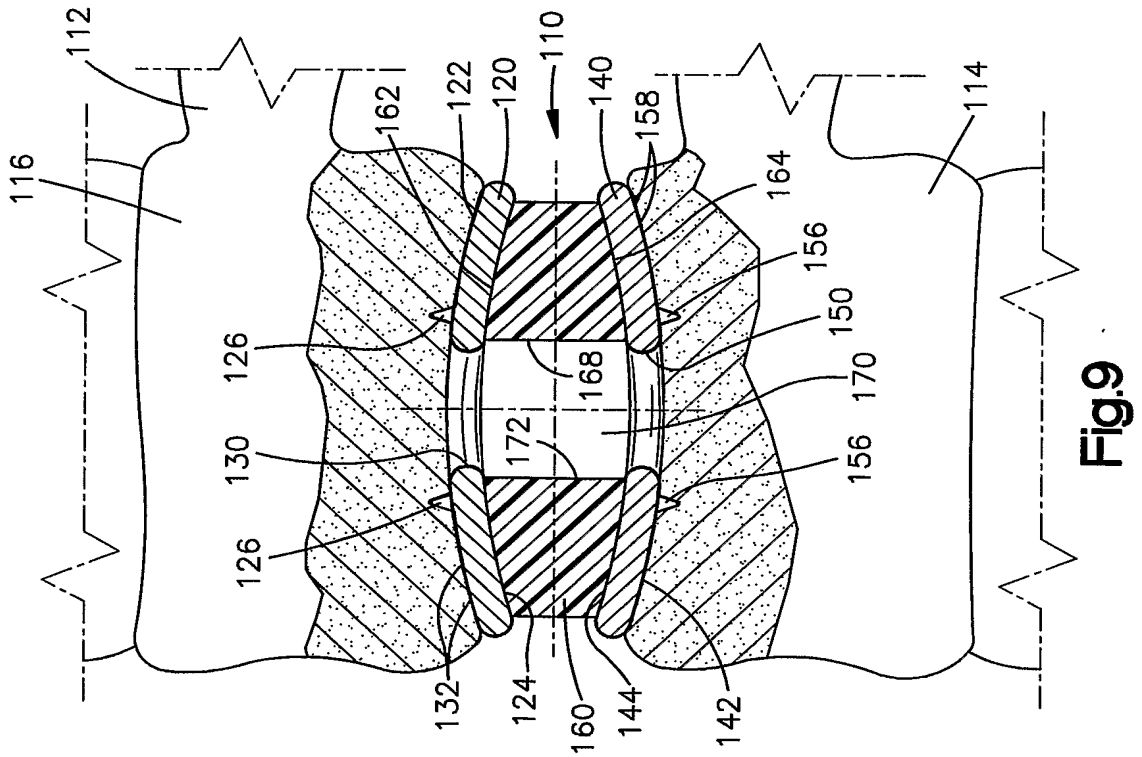
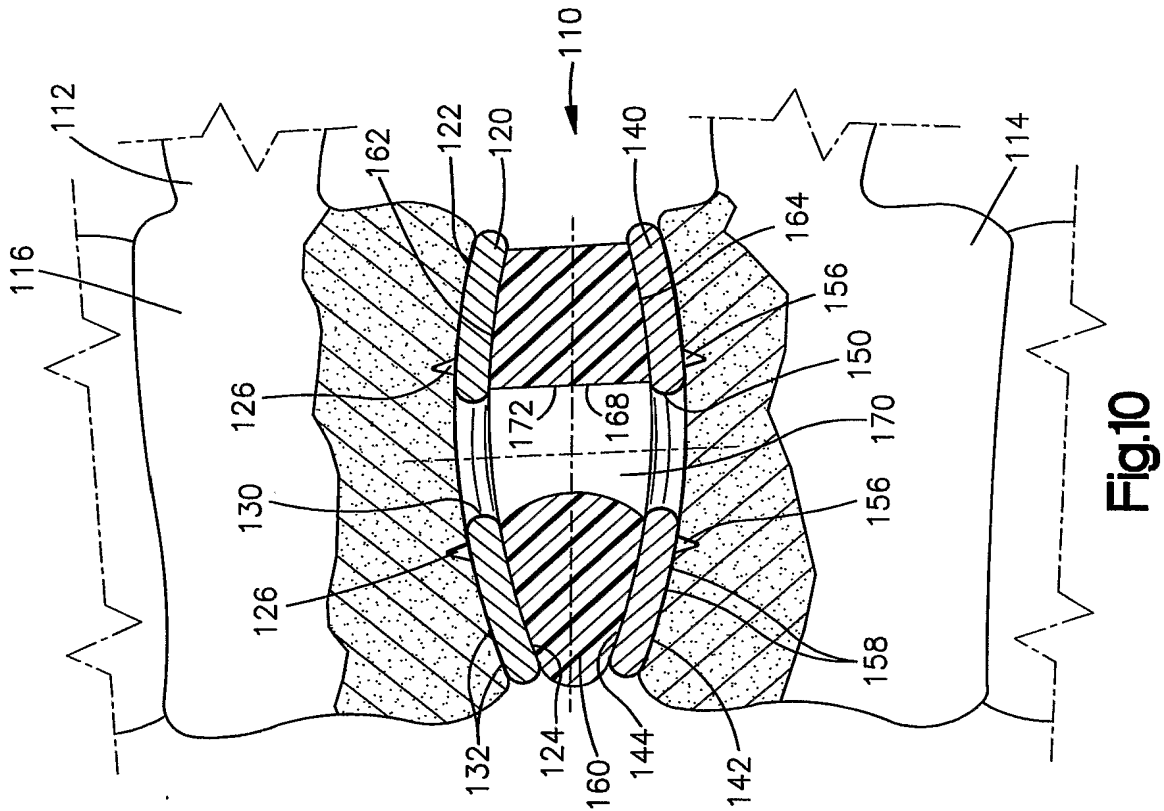


Fig.8



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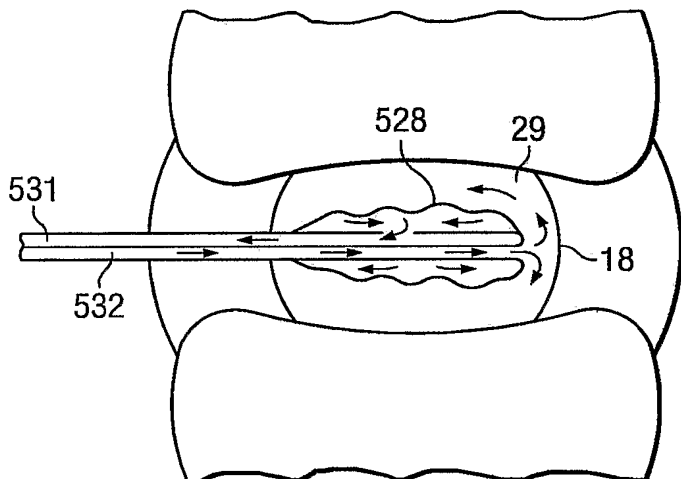
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(54) Title: METHOD AND APPARATUS FOR INTERVERTEBRAL DISC EXPANSION



(57) Abstract: An intervertebral disc is expanded and injected by forming and dilating an opening in the disc annulus and introducing an inflatable member into the disc nucleus pulposus. The inflatable member location within the nucleus pulposus is verified and the inflatable member is gradually inflated for augmenting a space in the nucleus pulposus. The internal pressure and expansion of the inflatable member are monitored. The inflatable member is subsequently deflated and a biomaterial is injected into the augmented space.

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METHOD AND APPARATUS FOR INTERVERTEBRAL DISC EXPANSION

5 Degenerated disc disease (DDD) leads to disc dehydration (black disc), gradual collapse, and ultimately leg and/or back pain. Interbody fusion is the current standard of care for DDD. It is desirable that this end-stage treatment be delayed as long as possible by early intervention with less invasive approaches. Disc augmentation by injection of a biomaterial into the disc space has been proposed previously as an early minimally
10 invasive treatment for a degenerated disc. Depending on the level of dehydration and collapse, injection of a biomaterial into the disc space of an intact disc (uncompromised annulus with no significant tears and original nucleus pulposus still in place) may require a high injection pressure and the injectable volume of biomaterial may be limited. High injection pressure increases the overall risk of the procedure including leakage, disc
15 rupture, etc. Limited injectable volume reduces the effectiveness of the treatment and may require multiple treatments to achieve desirable results.

In known methods for intervertebral disc expansion, a cut is made in the disc annulus and disc tissue is removed to provide a passage for the insertion of an expansion device, an expansion material, or both. Also, the nucleus pulposus is removed and
20 replaced by the expansion material and/or expansion device. Furthermore, degeneration of the disc is accelerated when an opening is cut into the disc annulus and tissue is removed. Therefore, what is needed is a device and method for accessing the nucleus pulposus for expansion of the disc such that no portion of the disc annulus and the nucleus pulposus are removed. Also, what is needed is an apparatus and method for a minimally invasive disc
25 treatment which increases injectable volume at a lower pressure.

One embodiment, accordingly, includes an expandable device for intervertebral disc expansion by means of an inflatable member insertable into a dilated opening in an intact intervertebral disc annulus and into a nucleus pulposus of the disc. An inflation
30 device is connected to controllably inflate the inflatable member within the nucleus pulposus without removing the nucleus pulposus.

A principal advantage of this embodiment is that it enables disc expansion with a percutaneous or minimally invasive approach. The disc expansion enables a larger volume of biomaterial injection per treatment. A larger volume of biomaterial injection reduces the number of treatments to achieve desirable level of augmentation. This treatment enables disc expansion without removal of the nucleus pulposus and helps determine the appropriate biomaterial volume prior to injection. Over-injection of the disc, and resulting pain and complications, can be minimized using the proposed device and method. Another advantage is that the disc remains intact such that no portion of the disc annulus or disc nucleus is removed.

Fig. 1 is a cross-sectional view illustrating an embodiment of a disc structure.

Figs. 2A-2F are cross-sectional views illustrating an embodiment of a disc expansion method and apparatus.

Fig. 3 is a cross-sectional view illustrating another embodiment of a disc expansion method and apparatus.

Fig. 4 is a cross-sectional view illustrating another embodiment of a disc expansion method and apparatus.

Figs. 5A-5D are cross-sectional views illustrating another embodiment of a disc expansion method and apparatus.

A disc structure 10, Fig. 1, generally comprises adjacent vertebrae 12 and 14 of the cervical, thoracic, or lumbar regions of the spine. An intervertebral disc 16 facilitates motion between the vertebrae 12 and 14 while absorbing shock and distributing loads. The disc 16 generally comprises a soft central core, i.e. the nucleus pulposus 18 (disc nucleus), that bears the majority of the load in a healthy disc, and a tough outer ring, i.e. the annulus fibrosis 20 (disc annulus), that surrounds and stabilizes the disc nucleus 18. A pair of cartilage endplates 22 are between each respective vertebrae 12 and 14, and the disc nucleus.

The method and apparatus are used following a patient diagnosis and selection for treatment, and in addition, a discogram to ensure disc annulus integrity.

The disc annulus 20, Fig. 2A, is punctured at 21 using a small diameter needle 24. A preferable needle size is 20 gauge. A small diameter (i.e. 1 to 3 mm) high-pressure balloon catheter 26, Fig. 2B, is introduced through the puncture 21 in the disc annulus 20. The location of a balloon 28 attached to catheter 26, in the disc nucleus 18 may be verified using fluoroscopy. The puncture required for insertion of devices for disc expansion and injection is small enough i.e. no greater than 3 mm, that the puncture may completely close, or close sufficiently that the injected biomaterial will remain captured. In the case of a biomaterial that sets up in the disc space after injection, capture of the injected biomaterial is assured. The use of an annulus closure device such as a plug or material such as a sealant is optional.

The balloon 28, Fig. 2C is gradually inflated with a saline and/or radiographic contrast medium such as sodium diatrizoate solution sold under the trademark Hypaque®, while monitoring the internal balloon pressure with a well known pressure gauge. Expansion of the balloon 28 is monitored using fluoroscopy. The rate of inflation and the pattern, size or shape of the balloon 28 can be varied between patients depending on disc condition. As the intradiscal pressure is increased and/or the endplates 22 are spread apart by the balloon 28, the disc annulus 20 is expected to stretch, as it is a viscoelastic material. The balloon may remain inflated from about 1 minute to about 1 hour, which may be varied for each patient. If significant expansion is required, the balloon may remain inflated up to 4 hours or it may be left in the disc space as a temporary implant up to 10 weeks.

As the balloon 28, Fig. 2D, is deflated, the disc 16 becomes slack with an augmented space and reduced intradiscal pressure. Injectable biomaterial 29 such as a collagen gel can be delivered to the disc nucleus 18, Fig. 2E, either through the same catheter, or a different needle 30 may be used after the balloon catheter 26 is deflated and removed. If the same catheter is used for injection, the injection can be done simultaneously as the balloon 28 is being deflated, as will be discussed below in greater detail.

Examples of biomaterials 29 which may be used for disc augmentation can be natural or synthetic, resorbable or non-resorbable. Natural materials include various forms of collagen that are derived from collagen-rich or connective tissues such as an

intervertebral disc, fascia, ligament, tendon, skin, demineralized bone matrix, etc.

Material sources include autograft, allograft, xenograft, human-recombinant origin, etc.

Natural materials also include various forms of polysaccharides that are derived from animals or vegetation such as hyaluronic acid, chitosan, cellulose, agar, etc. Other natural materials include other proteins such as fibrin, albumin, silk, elastin and keratin. Synthetic materials include various implantable polymers or hydrogels such as silicone, polyurethane, silicone-polyurethane copolymers, polyolefin, polyester, polyacrylamide, polyacrylic acid, polyvinyl alcohol, polyethylene oxide, polyethylene glycol, polylactide, polyglycolide, poly(lactide-co-glycolide), poly(dioxanone), poly(ϵ -caprolactone), poly(hydroxybutyrate), poly(hydroxyvalerate), tyrosine-based polycarbonate, polypropylene fumarate or combinations thereof. It is preferred that the biomaterial can undergo transition from a flowable to a non-flowable state shortly after injection. This can typically be achieved by adding a crosslinking agent to the biomaterial before, during, or after injection.

Proteoglycans may also be included in the injectable biomaterial 29 to attract and/or bind water to keep the disc nucleus 18 hydrated. Similarly, growth factors (e.g. transforming growth factor beta, bone morphogenetic proteins, fibroblast growth factors, platelet-derived growth factors, insulin-like growth factors, etc.) and/or other cells (e.g., intervertebral disc cells, stem cells, etc.) to promote healing, repair, regeneration and/or restoration of the disc, and/or to facilitate proper disc function, may also be included. Additives appropriate for use in the claimed invention are known to persons skilled in the art, and may be selected without undue experimentation.

Injectable biomaterial 29 is preferably mixed with the radiographic contrast medium prior to injection into the disc nucleus 18. This will allow the injection to be monitored using fluoroscopy. The catheter 26 or the needle 30, Fig. 2F, used for injection, is removed after an appropriate volume of biomaterial is deposited in the disc nucleus 18. As an alternative to withdrawing the balloon 28, as illustrated in Fig. 2D above, a balloon 128, Fig. 3 may be detachable at 127 from a catheter 126, and may remain inflated in the disc nucleus 18 as an implant. In the case of the detachable balloon 128, it may be advantageous to inject a biomaterial which, after injection, takes a set in an elastic or gel

form. This could be accomplished by injecting a second material with the biomaterial which would alter the form of the injected material.

As an alternative to inflating balloon 28 with the radiographic contrast medium as described above, the balloon 28 may be inflated by injection of the biomaterial 29. This would be advantageous in the embodiment described above where the balloon is detachable and where the biomaterial may take a set after injection.

In the case of direct injection of biomaterial 29 into the inflatable balloon member 28, the balloon 28 may be porous or permeable (e.g. woven fabric, mesh structure, perforated membrane, etc.) to allow material or fluid migration out of the inflatable member during or after injection.

Alternatively, a modified balloon 28a, Fig. 4, may be of a shape including a profiler for inflating in a pattern for spreading the endplates 22 apart. That is, the balloon 28a is manufactured to expand to a suitable shape to better accomplish spreading the endplates 22 apart rather than to conform to the shape of disc nucleus 18 as in Fig. 2C.

An alternative balloon catheter may be used, i.e. a double lumen catheter which can be used for injection as the balloon is being deflated. In an alternative embodiment, Fig. 5A illustrates a balloon catheter 526 introduced into the disc nucleus 18. The catheter 526 includes a first channel 531, a second channel 532 and a balloon 528. The saline and/or radiographic contrast medium is injected into balloon 528 via the first channel 531 to inflate balloon for expansion of the disc nucleus 18. In Fig. 5B, the inflated balloon 528 remains inflated in the disc nucleus 18 for an appropriate amount of time to stretch the annulus fibrosis and/or expand the nuclear disc space. In Fig. 5C, an appropriate biomaterial 29 is injected into the disc nucleus 18 via the second channel 532 in catheter 526 while the balloon inflating medium is simultaneously evacuated via the first channel 531. In Fig. 5D, the deflated balloon 528 is withdrawn with catheter 526 from the disc nucleus 18 and the injected biomaterial 29 remains within the disc nucleus 18.

As a result, one embodiment provides an apparatus including a high-pressure balloon catheter with a small shaft diameter (3mm or smaller, preferably 2 mm or smaller, most preferably 1mm or smaller). The catheter has a pointed tip for puncturing an intact disc annulus and insertion of the balloon section into the nuclear disc region. The catheter either has rigid shaft or is supported by a rigid guide-needle during penetration into the

disc. For a rigid shaft, the catheter can be made of metal tubing. For a flexible shaft, the catheter can be made of polymeric tubing and is supported with a rigid guide-needle or guide-wire. If a guide-needle is used, the catheter can be double lumen. The balloon has an appropriate final volume of from about 0.1 cc to about 8.0 cc, preferably up to 5.0 cc and dimensions (length = 5-40 mm, preferably 10-30 mm; diameter = 3-20 mm, preferably 5-15 mm) to fit the nuclear disc region. The balloon can be of various shapes; conical, spherical, square, long conical, long spherical, long square, tapered, stepped, dog bone, offset, or combinations thereof. Balloons can be made of various polymeric materials such as polyethylene terephthalates, polyolefins, polyurethanes, nylon, polyvinyl chloride, silicone, polyetheretherketone, polylactide, polyglycolide, poly(lactide-co-glycolide), poly(dioxanone), poly(ϵ -caprolactone), poly(hydroxybutyrate), poly(hydroxyvalerate), tyrosine-based polycarbonate, polypropylene fumarate or combinations thereof.

Another embodiment provides first, a determination that the treated disc has a competent and intact annulus fibrosis for safe expansion and effective containment of the subsequently injected biomaterial. After the annulus quality and integrity are verified using discography, the disc expansion device with the smallest shaft diameter possible, is inserted into the center of the disc. Insertion of the device can be done percutaneously, preferably under fluoroscopic guidance. The balloon is gradually inflated with radio-contrast fluid or saline to pressurize the disc, and thereby, stretch the annulus fibrosis. After a predetermined inflation time, the balloon is deflated and removed from the disc space. The biomaterial is subsequently injected into the disc using a small-diameter hypodermic needle until a desirable injection volume is achieved. When a double-lumen catheter is employed, the biomaterial can be injected into the disc through the same catheter during or after balloon deflation. The whole procedure is preferably done under fluoroscopic guidance.

The foregoing has described an apparatus and method for expansion of an intervertebral disc prior to its augmentation with an injectable biomaterial. Disc expansion prepares the disc annulus to receive a desirable or effective volume of injectable material in a single treatment. Because the annulus fibrosis is a viscoelastic material, it can be temporarily stretched as the disc is expanded under pressure.

Although illustrative embodiments have been shown and described, a wide range of modification, change and substitution is contemplated in the foregoing disclosure and in some instances, some features of the embodiments may be employed without a corresponding use of other features. Accordingly, it is appropriate that the appended
5 claims be construed broadly and in a manner consistent with the scope of the embodiments disclosed herein.

What is claimed is:

1. An expandable device for intervertebral disc expansion comprising:

5 an inflatable member insertable into a dilated opening in an intact intervertebral disc annulus and into a nucleus pulposus of the disc; and

an inflation device connected to the inflatable member for controllable inflation of the inflatable member within the nucleus pulposus without removing any of the nucleus pulposus.

10 2. The expandable device as defined in claim 1 wherein the inflatable member has a controlled expanded shape conforming substantially to the nucleus pulposus shape.

15 3. The expandable device as defined in claim 2 wherein the inflatable member has an inflated volume of from about 0.1 cc to about 8.0 cc.

4. The expandable device as defined in claim 1, further comprising:

a profiler formed in the inflatable member and shaped for spreading vertebral endplates apart in response to expansion of the inflatable member.

20 5. The device as defined in claim 1 wherein the inflatable member is detachable from the inflation device.

25 6. The device as defined in claim 1 wherein the inflatable member is inflated with a biomaterial.

7. The device as defined in claim 6 wherein the inflatable member is porous and permeable.

30 8. The device as defined in claim 6 wherein the biomaterial material is provided as a formulation that includes growth factors.

9. The device as defined in claim 6 wherein the biomaterial material is provided as a formulation that includes one or more other types of cells effective to promote healing, repair, regeneration and/or restoration of the disc, and/or to facilitate proper disc function.

5

10. The device as defined in claim 6 wherein the biomaterial is altered from a flowable state to a non-flowable state after inflation of the inflatable member.

11. The device as defined in claim 6 wherein the biomaterial is a synthetic material.

10

12. The device as defined in claim 11 wherein the synthetic material is a polymer.

13. The device as defined in claim 11 wherein the synthetic material is a hydrogel.

15

14. The device as defined in claim 6 wherein the biomaterial is a natural material.

15. The device as defined in claim 14 wherein the natural material is a collagen material.

20

16. The device as defined in claim 14 wherein the natural material is a polysaccharide material.

17. A method for expanding and injecting an intervertebral disc comprising:

25

forming and dilating an opening in a disc annulus without removing any of the disc annulus;

introducing an inflatable member through the dilated opening in the disc annulus and into a nucleus pulposus of the disc without removing any of the nucleus pulposus;

30

verifying location of the inflatable member in the nucleus pulposus;
gradually inflating the inflatable member for augmenting a space in the nucleus pulposus;

monitoring the inflatable member internal pressure and expansion;
deflating the inflatable member; and
injecting a biomaterial into the augmented space.

- 5 18. The method as defined in claim 17 comprising:
 injecting the biomaterial through a passage in the inflatable member
simultaneously with the deflation of the inflatable member.
19. The method as defined in claim 17 comprising:
10 removing the inflatable member from the disc; and
 inserting an injection member into the augmented space for injecting the
biomaterial.
20. The method as defined in claim 17 further comprising:
15 providing the biomaterial as a formulation that includes growth factors.
21. The method as defined in claim 17 further comprising:
 providing the biomaterial as a formulation that includes one or more other
types of cells effective to promote healing, repair, regeneration and/or restoration of the
20 disc, and/or to facilitate proper disc function.
22. The method as defined in claim 17 comprising:
 diagnosing for patient compatibility to receive treatment.
23. The method as defined in claim 22 comprising:
25 performing a discogram on the patient to ensure disc annulus integrity.
24. The method as defined in claim 17 wherein the inflatable member location is
verified by fluoroscopy.

25. The method as defined in claim 17 wherein the inflatable member is inflated with a radio contrast material.

26. The method as defined in claim 17 wherein the inflatable member expansion is monitored by fluoroscopy.

27. The method as defined in claim 26 wherein the inflatable member pressure is monitored by a pressure gauge.

28. The method as defined in claim 17 wherein the inflatable member has an inflated volume of from about 0.1 cc to about 8.0 cc.

29. The method as defined in claim 28 wherein the inflatable member includes a profiler shaped for spreading vertebral endplates apart in response to expansion of the inflatable member.

30. The method as defined in claim 17 further comprising:
external means for expanding an intervertebral space occupied by the disc.

31. An expansion and injection system for an intervertebral disc comprising:
an instrument for forming and dilating an opening in a disc annulus without removing any of the disc annulus;

an inflatable member insertable through the dilated opening in the disc annulus and into a nucleus pulposus of the disc without removing any of the nucleus pulposus;

means for verifying inflatable member location in the nucleus;
means for gradually inflating the inflatable member for augmenting a space in the nucleus pulposus;

a gauge for monitoring the inflatable member pressure;
means for deflating the inflatable member; and

an injection instrument for injecting a biomaterial into the augmented space.

32. The system as defined in claim 31 wherein the biomaterial is injected through a passage in the inflatable member simultaneously with the deflation of the inflatable member.

33. The system as defined in claim 31 wherein the inflatable member is removed from the disc; and

an injection member is inserted into the augmented space for injecting the biomaterial.

34. The system as defined in claim 31 further comprising:

providing the biomaterial as a formulation that includes growth factors.

35. The system as defined in claim 31 further comprising:

providing the biomaterial as a formulation that includes one or more other types of cells effective to promote healing, repair, regeneration and/or restoration of the disc, and/or to facilitate proper disc function.

36. The system as defined in claim 31 wherein the inflatable member location is verified by fluoroscopy.

37. The system as defined in claim 31 wherein the inflatable member is inflated with a radio contrast material.

38. The system as defined in claim 31 wherein the inflatable member expansion is monitored by fluoroscopy.

39. The system as defined in claim 38 wherein the inflatable member pressure is monitored by a pressure gauge.

40. The system as defined in claim 31 wherein the inflatable member has an inflated volume of from about 0.1 cc to about 8.0 cc.

5 41. The system as defined in claim 31 wherein the inflatable member includes a profiler shaped for spreading vertebral endplates apart in response to expansion of the inflatable member.

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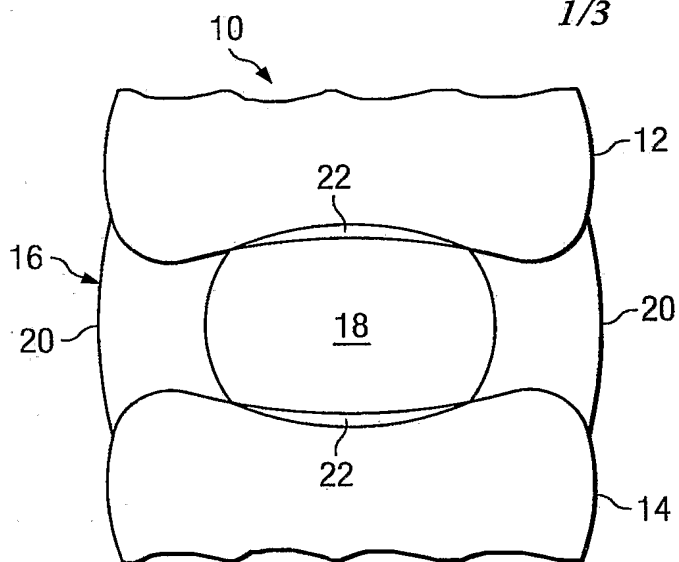


Fig. 1

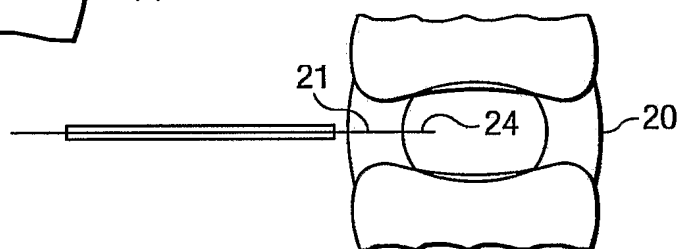


Fig. 2A

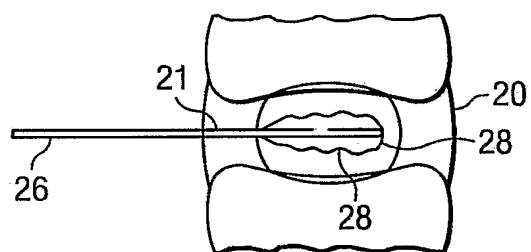


Fig. 2B

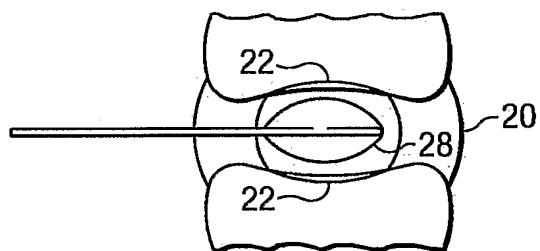


Fig. 2C

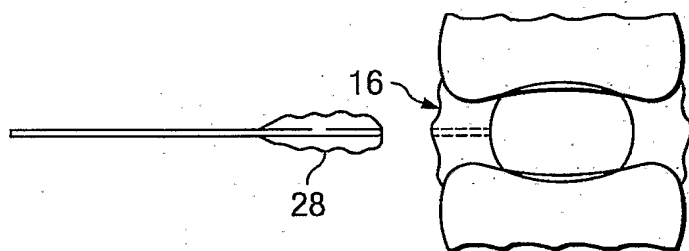


Fig. 2D

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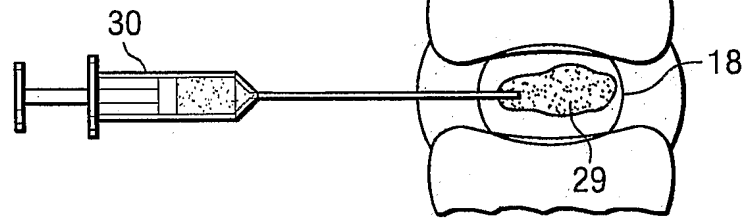


FIG. 2E

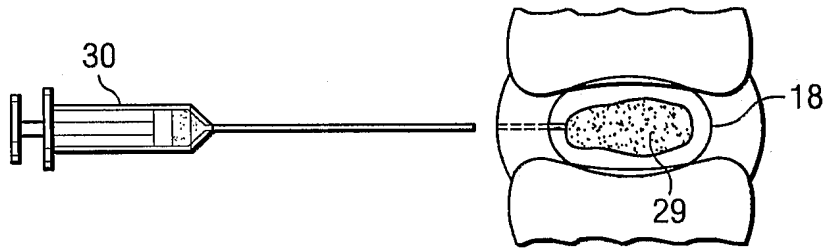


FIG. 2F

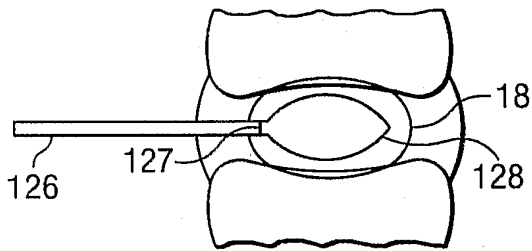


FIG. 3

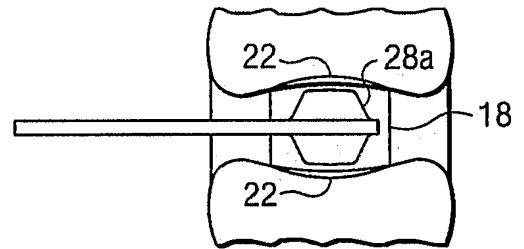


FIG. 4

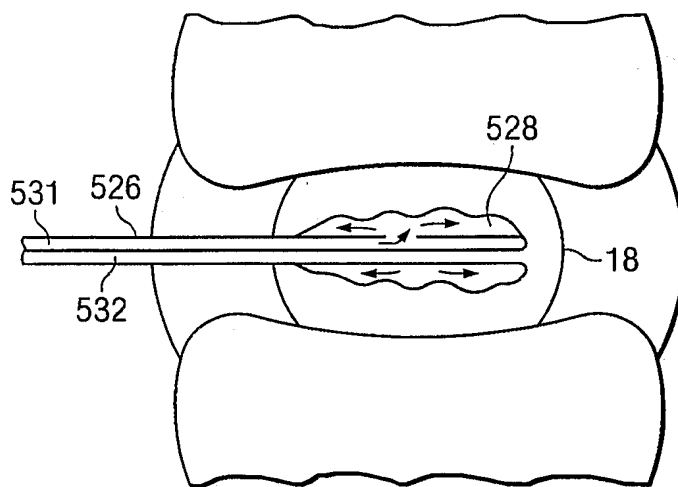


FIG. 5A

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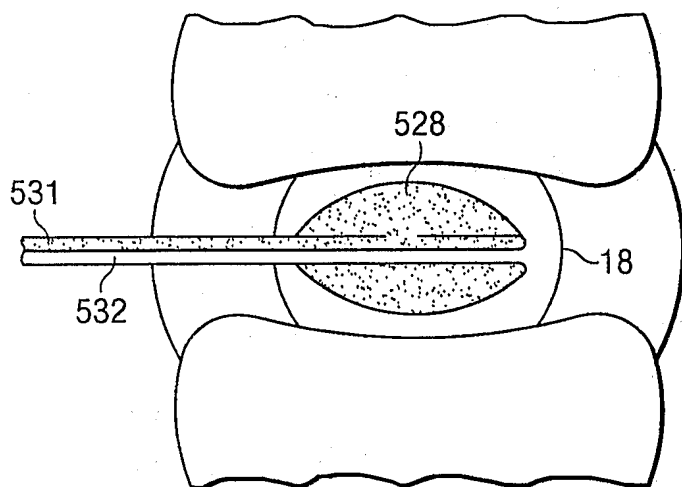


Fig. 5B

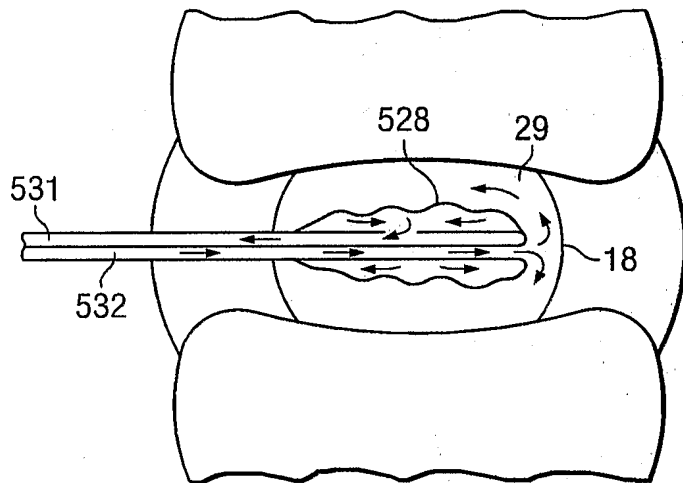


Fig. 5C

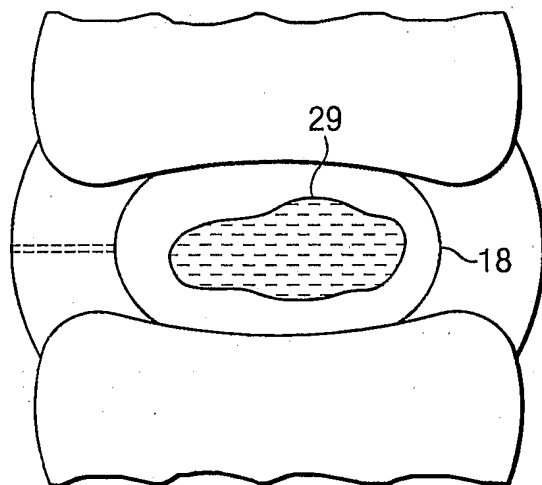


Fig. 5D

INTERNATIONAL SEARCH REPORT

national Application No

PCT/US 03/38957

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44 A61F2/46 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/17825 A (DISC DYNAMICS INC ;HUDGINS ROBERT GARRYL (US); YUAN HANSEN A (US);) 7 March 2002 (2002-03-07)	1-12
Y	page 4, line 24 -page 13, line 20 page 15, line 14 - line 22 page 16, line 8 - line 15 page 42, line 24 -page 43, line 5 page 44, line 16 -page 46, line 10 page 54, line 10 -page 57, line 14 ---	9, 31, 33-41
X	US 6 264 659 B1 (GUAGLIANO PETER A ET AL) 24 July 2001 (2001-07-24)	1, 5
Y	column 5, line 54 -column 7, line 2 --- -/--	31, 33, 36, 38-41



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/38957

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 436 119 B1 (ERB STEVEN J ET AL) 20 August 2002 (2002-08-20) column 2, line 40 -column 3, line 63 ----	31
X	US 2002/177866 A1 (WEIKEL STUART ET AL) 28 November 2002 (2002-11-28)	1,2,5-7, 11-13
Y	paragraph '0010! - paragraph '0011! paragraph '0015! paragraph '0081! - paragraph '0085! ----	31,37
Y	DE 199 59 975 A (EFMT ENTWICKLUNGS UND FORSCHUN) 26 July 2001 (2001-07-26) column 1, line 68 -column 2, line 5 ----	9,35
Y	US 6 099 514 A (ASHLEY JOHN ET AL) 8 August 2000 (2000-08-08) column 16, line 50 -column 17, line 17 ----	34
A	US 2002/045942 A1 (HAM MICHAEL J) 18 April 2002 (2002-04-18) paragraph '0018! paragraph '0022! paragraph '0040! -----	31-41

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/38957

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-30
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/38957

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0217825	A	07-03-2002	AU 8548601 A	13-03-2002
			CN 1340330 A	20-03-2002
			EP 1313411 A2	28-05-2003
			JP 2004507319 T	11-03-2004
			WO 0217825 A2	07-03-2002
			US 2003195628 A1	16-10-2003
			US 2003220649 A1	27-11-2003
US 6264659	B1	24-07-2001	US 6183518 B1	06-02-2001
			US 6206921 B1	27-03-2001
			AU 3498300 A	14-09-2000
			WO 0049978 A1	31-08-2000
			US 6436143 B1	20-08-2002
US 6436119	B1	20-08-2002	NONE	
US 2002177866	A1	28-11-2002	CA 2444557 A1	31-10-2002
			EP 1379185 A1	14-01-2004
			WO 02085227 A1	31-10-2002
DE 19959975	A	26-07-2001	DE 19959975 A1	26-07-2001
US 6099514	A	08-08-2000	US 6290715 B1	18-09-2001
			US 2003181964 A1	25-09-2003
			US 6547810 B1	15-04-2003
			AU 4996097 A	15-05-1998
			CA 2269282 A1	30-04-1998
			EP 1006885 A2	14-06-2000
			JP 2002515793 T	28-05-2002
			US 6283960 B1	04-09-2001
			WO 9817190 A2	30-04-1998
			US 6126682 A	03-10-2000
			US 6258086 B1	10-07-2001
			US 6261311 B1	17-07-2001
			US 6517568 B1	11-02-2003
			US 2001023348 A1	20-09-2001
			US 2001031963 A1	18-10-2001
			US 5980504 A	09-11-1999
			US 6007570 A	28-12-1999
			US 6095149 A	01-08-2000
US 2002045942	A1	18-04-2002	AU 8854501 A	29-04-2002
			WO 0232349 A1	25-04-2002

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(74) Agent: **LONDA, Bruce, S.**; Norris, McLaughlin & Marcus, P.A., 220 East 42nd Street, 30th Floor, New York, NY 10017 (US).

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(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

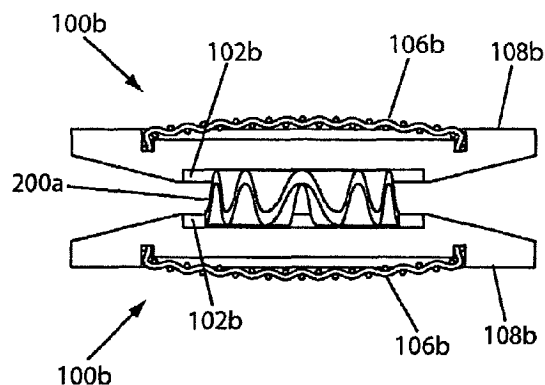
Published:

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10 April 2003

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ARTIFICIAL INTERVERTEBRAL DISC HAVING A WAVE WASHER FORCE RESTORING ELEMENT



(57) Abstract: An artificial disc having a pair of opposing plates (100b) for seating against opposing vertebral bone surfaces, separated by a wave washer (200a) having a circumferential extent surrounding a central bore. Various wave washer embodiments disclosed include circumferential extents that are ring-shaped, spiral-shaped, straight, bowed, grooved, wavy, thinning, thickening, and slotted. Various central bores disclosed include simple bores and bores that form a curved socket. Various plate embodiments disclosed include plates having, on inwardly facing surfaces, a flat surface, a circular recess, a ball-shaped protuberance that is mateable with the curvate socket. The wave washers (200a) are disposable between the plates (100b), through various disclosed coupling, so that the plates (100b) compress, rotate and angulate freely relative to one another, enabling the artificial disc to mimic a healthy

natural intervertebral disc.

WO 03/007780 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/19659

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/44

US CL :623/17.13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.13, 17.11,17.15,17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,309,777 A (PATIL) 12 January 1982, see whole document.	1-97
A	US 5,458,642 A (BEER et al) 17 October 1995, see whole document.	1-97
A	US 6,231,609 B1 (MEHDIZADEH) 15 May 2001, see whole document.	1-97

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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ARTIFICIAL INTERVERTEBRAL DISC HAVING A WAVE WASHER FORCE RESTORING ELEMENT

FIELD OF THE INVENTION

5 [0001] This invention relates generally to a spinal implant assembly for implantation into the intervertebral space between adjacent vertebral bones to simultaneously provide stabilization and continued flexibility and proper anatomical motion, and more specifically to such a device that utilizes a wave washer force restoring element.

BACKGROUND OF THE INVENTION

10 [0002] The bones and connective tissue of an adult human spinal column consists of more than 20 discrete bones coupled sequentially to one another by a tri-joint complex that consists of an anterior disc and the two posterior facet joints, the anterior discs of adjacent bones being cushioned by cartilage spacers referred to as
15 intervertebral discs. These more than 20 bones are anatomically categorized as being members of one of four classifications: cervical, thoracic, lumbar, or sacral. The cervical portion of the spine, which comprises the top of the spine, up to the base of the skull, includes the first 7 vertebrae. The intermediate 12 bones are the thoracic vertebrae, and connect to the lower spine comprising the 5 lumbar vertebrae. The
20 base of the spine is the sacral bones (including the coccyx). The component bones of the cervical spine are generally smaller than those of the thoracic spine, which are in turn smaller than those of the lumbar region. The sacral region connects laterally to the pelvis. While the sacral region is an integral part of the spine, for the purposes of fusion surgeries and for this disclosure, the word spine shall refer only to the cervical,
25 thoracic, and lumbar regions.

 [0003] The spinal column is highly complex in that it includes these more than 20 bones coupled to one another, housing and protecting critical elements of the nervous system having innumerable peripheral nerves and circulatory bodies in close proximity. In spite of these complications, the spine is a highly flexible structure,
30 capable of a high degree of curvature and twist in nearly every direction.

 [0004] Genetic or developmental irregularities, trauma, chronic stress, tumors, and degenerative wear are a few of the causes that can result in spinal pathologies for which surgical intervention may be necessary. A variety of systems have been

disclosed in the art that achieve immobilization and/or fusion of adjacent bones by implanting artificial assemblies in or on the spinal column. The region of the back that needs to be immobilized, as well as the individual variations in anatomy, determine the appropriate surgical protocol and implantation assembly. With respect to the failure of the intervertebral disc, the interbody fusion cage has generated substantial interest because it can be implanted laparoscopically into the anterior of the spine, thus reducing operating room time, patient recovery time, and scarification.

[0005] Referring now to Figures 7 and 8, in which a side perspective view of an intervertebral body cage and an anterior perspective view of a post implantation spinal column are shown, respectively, a more complete description of these devices of the prior art is herein provided. These cages generally comprise tubular metal body 12 having an external surface threading 14. They are inserted transverse to the axis of the spine 16, into preformed cylindrical holes at the junction of adjacent vertebral bodies (in Figure 8 the pair of cages 10 are inserted between the fifth lumbar vertebra (L5) and the top of the sacrum (S1)). Two cages 10 are generally inserted side by side with the external threading 14 tapping into the lower surface of the vertebral bone above (L5), and the upper surface of the vertebral bone (S1) below. The cages 10 include holes 18 through which the adjacent bones are to grow. Additional materials, for example autogenous bone graft materials, may be inserted into the hollow interior 20 of the cage 10 to incite or accelerate the growth of the bone into the cage. End caps (not shown) are often utilized to hold the bone graft material within the cage 10.

[0006] These cages of the prior art have enjoyed medical success in promoting fusion and grossly approximating proper disc height. It is, however, important to note that the fusion of the adjacent bones is an incomplete solution to the underlying pathology as it does not cure the ailment, but rather simply masks the pathology under a stabilizing bridge of bone. This bone fusion limits the overall flexibility of the spinal column and artificially constrains the normal motion of the patient. This constraint can cause collateral injury to the patient's spine as additional stresses of motion, normally borne by the now-fused joint, are transferred onto the nearby facet joints and intervertebral discs. It would therefore, be a considerable advance in the art to provide an implant assembly which does not promote fusion, but, rather, which nearly completely mimics the biomechanical action of the natural disc cartilage, thereby permitting continued normal motion and stress distribution.

[0007] It is, therefore, an object of the invention to provide an intervertebral spacer that stabilizes the spine without promoting a bone fusion across the intervertebral space.

[0008] It is further an object of the invention to provide an implant device that stabilizes the spine while still permitting normal motion.

[0009] It is further an object of the invention to provide a device for implantation into the intervertebral space that does not promote the abnormal distribution of biomechanical stresses on the patient's spine.

[0010] It is further an object of the invention to provide an artificial disc that has an plate attachment device (for attaching the plates of the artificial disc to the vertebral bones between which the disc is implanted) with superior gripping and holding strength upon initial implantation and thereafter.

[0011] It is further an object of the invention to provide an artificial disc plate attachment device that deflects during insertion of the artificial disc between vertebral bodies.

[0012] It is further an object of the invention to provide an artificial disc plate attachment device that conforms to the concave surface of a vertebral body.

[0013] It is further an object of the invention to provide an artificial disc plate attachment device that does not restrict the angle at which the artificial disc can be implanted.

[0014] It is further an object of the invention to provide an artificial disc that supports tension loads.

[0015] It is further an object of the invention to provide an artificial disc that provides a centroid of motion centrally located within the intervertebral space.

[0016] Other objects of the invention not explicitly stated will be set forth and will be more clearly understood in conjunction with the descriptions of the preferred embodiments disclosed hereafter.

SUMMARY OF THE INVENTION

[0017] The preceding objects are achieved by the invention, which is an artificial intervertebral disc or intervertebral spacer device comprising a pair of support members (e.g., spaced apart plates), each with an exterior surface. Because the artificial disc is to be positioned between the facing surfaces of adjacent vertebral bodies, the plates are arranged in a substantially parallel planar alignment (or slightly

offset relative to one another in accordance with proper lordotic angulation) with the exterior surfaces facing away from one another. The plates are to mate with the vertebral bodies so as to not rotate relative thereto, but rather to permit the spinal segments to axially compress and bend relative to one another in manners that mimic the natural motion of the spinal segment. This natural motion is permitted by the performance of a spring disposed between the secured plates, and the securing of the plates to the vertebral bone is achieved through the use of a vertebral body contact element including, for example, a convex mesh attached to the exterior surface of each plate. Each convex mesh is secured at its perimeter, by laser welds, to the exterior surface of the respective plate. While domed in its initial undeflected conformation, the mesh deflects as necessary during insertion of the artificial disc between vertebral bodies, and, once the artificial disc is seated between the vertebral bodies, the mesh deforms as necessary under anatomical loads to reshape itself to the concave surface of the vertebral endplate. Thus, the wire mesh is deformably reshapeable under anatomical loads such that it conformably deflects against the concave surface to securably engage the vertebral body endplate. Stated alternatively, because the wire mesh is convexly shaped and is secured at its perimeter to the plate, the wire mesh is biased away from the plate but moveable toward the plate (under a load overcoming the bias; such a load is present, for example, as an anatomical load in the intervertebral space) so that it will securably engage the vertebral body endplate when disposed in the intervertebral space. This affords the plate having the mesh substantially superior gripping and holding strength upon initial implantation, as compared with other artificial disc products. The convex mesh further provides an osteoconductive surface through which the bone may ultimately grow. The mesh preferably is comprised of titanium, but can also be formed from other metals and/or non-metals. Inasmuch as the mesh is domed, it does not restrict the angle at which the artificial disc can be implanted. It should be understood that while the flexible dome is described herein preferably as a wire mesh, other meshed or solid flexible elements can also be used, including flexible elements comprises of non-metals and/or other metals. Further, the flexibility, deflectability and/or deformability need not be provided by a flexible material, but can additionally or alternatively be provided mechanically or by other means.

[0018] To enhance the securing of the plates to the vertebral bones, each plate further comprises at least a lateral porous ring (which may be, for example, a sprayed

deposition layer, or an adhesive applied beaded metal layer, or another suitable porous coating known in the art). This porous ring permits the long-term ingrowth of vertebral bone into the plate, thus permanently securing the prosthesis within the intervertebral space. The porous layer may extend beneath the domed mesh as well,
5 but is more importantly applied to the lateral rim of the exterior surface of the plate that seats directly against the vertebral body.

[0019] The spring disposed between the plates provides a strong restoring force when a compressive load is applied to the plates, and also permits rotation and angulation of the two plates relative to one another. While a wide variety of
10 embodiments are contemplated, a preferred spring includes a wave washer utilized as the restoring force providing element. In general, a wave washer is one of the strongest configurations for a spring, and is highly suitable for use as a force restoring providing subassembly for use in an intervertebral spacer element that must endure considerable cyclical loading in an active human adult. A compressive load applied
15 to the plates causes a corresponding compression of the wave washer, which in turn causes a restoring force to be applied to the plates. The wave washer deflects appropriately under the load, only to spring back to its undeflected shape upon the unloading.

[0020] In particular, in order for the overall device to mimic the mechanical
20 flexibility of the natural disc, it is desirable that the spring provide restoring forces that (1) are directed outward against the opposing plates, when a compressive load is applied to the plates; (2) that permit lateral bending and flexion and extension bending of the plates relative to parallel; (3) that do not permit lateral translation of the plates relative to one another during such bending; and (4) that do not
25 substantially interfere with the rotation of the opposing plates relative to one another. The wave washers disclosed herein provide such functionality.

[0021] The wave washers of the invention have a circumferential extent surrounding a central bore. The circumferential extent is concentrically wavy, such that the extent undulates along a concentric path around the central bore to form
30 radially extending valleys and peaks, while preferably maintaining a constant radius. Stated equivalently with regard to the most basic wave washer embodiments of the invention, which resemble traditional wave washers, the wave washer is a simple round washer having a circumferential extent that comprises a flat round ring, except that while maintaining a constant curvature of radius in the plane normally defined

by the washer, the circumferential extent rises and falls in a wave-like curve.

Whereas a standard (non-wave) washer has a circumferential extent that is confined to the x-y plane, the wave washer has a circumferential extent that extends in the x-y plane but undulates in the z-axis. Herein, the top and bottom of a wave washer shall
5 be defined as the planes defined by the lowest and highest points of the undulations, respectively. In some embodiments, the circumferential extent is continuous (i.e., has no slots). In other embodiments, the circumferential extent has at least one radially extending slot. In still other embodiments, the circumferential extent has at least one radially extending and spiraling slot. The thickness of the circumferential extent; the
10 frequency, amplitude, and configuration of the waves; and/or the number and configuration of the slots can be varied to accommodate any desired application, inasmuch as varying the dimensions will affect the behavior of the wave washer in expansion and retraction.

[0022] The restoring force of a wave washer is proportional to the elastic
15 properties of the material. As a compressive load is applied to the wave washer, the forces are directed down onto the peaks and up against the valleys. A significant fraction of these forces are immediately translated into hoop stresses that apply stresses directly toward radially expanding the wave washer. This hoop stress is also counterbalanced by the material strength of the wave washer. The strain of the
20 material causes a deflection in the height of the washer and a slight radial expansion. The slots in the slotted embodiments permit the compressive load that is applied to the wave washer down onto the peaks and up against the valleys to cause the wave washer to deflect such that the slots close. Thus, a difference between a slotted washer and a continuous washer is that the continuous washer responds to a
25 compressive load by primarily deflecting radially (with a very high stress to deflection ratio), whereas the slotted washer primarily deflects circumferentially, closing the slots (which is characteristic of a much lower stress to deflection ratio). Stated equivalently, a wave washer responds to a compressive load by deflecting compressively, and either radially or circumferentially. With at least one slot formed
30 in the washer, it expands and retracts far more elastically than a continuous washer. It should be understood that wave washers other than those shown are contemplated by the invention, including but not limited to wave washers having a circumferential extent that does not have a uniformly wide radius.

[0023] As described above, the most basic wave washer of the invention has a

circumferential extent that defines a circumference of 360 degrees (or less if the wave washer includes a radial slot that passes completely through the circumferential extent). Another wave washer embodiment of the invention, instead of being ring-shaped, is spiral-shaped, having a circumferential extent that defines a circumference of more than 360 degrees, and preferably more than 720 degrees, or more depending on the specific anatomical needs of the patient. The undulations of the wave washer in the z-axis may be such that the arches are aligned, or misaligned. In yet another wave washer embodiment of the invention, instead of using a spiral-shaped wave washer, multiple concentric ring-shaped wave washers can be used in conjunction with one another to achieve a similar functional result.

[0024] Still another wave washer embodiment of the invention is also spiral-shaped, but has an amplitude of the undulations that decreases in the radial direction. The wave washer thereby takes on the edge-on appearance of a spiral galaxy, having a thicker central portion, and a flatter edge. In this case, the restoring force varies according to the number of spirals of the washer and according to the number of spirals that are engaged (more radially distal spirals are engaged as the deflection of the washer increases). More specifically, as a compressive load is applied by a pair of plates against the top and bottom of a spiral wave washer, the forces are first directed against the peaks of the undulating waves at the center of the spiral, and are then increasingly directed against the peaks of the outer portions of the spiral. In a further wave washer embodiment of the invention, instead of using a spiral-shaped wave washer with radially decreasing undulation amplitudes, multiple concentric ring-shaped wave washers can be used in conjunction with one another, positioned so that those with smaller undulation amplitudes are more radially distant from the center of the grouped washers, to achieve a similar functional result. It should be understood that in either of these types of embodiments, the wave washers can be formed such that the undulation amplitudes increase, rather than decrease, with their radial distance from the center of the washer, or such that the undulation amplitudes vary in size either randomly or according to other patterns.

[0025] With regard to additional wave washer embodiments, changing the configuration of the circumferential extent in other ways modifies the magnitude of the compressive load support and restoring force provided by the wave washer. For clarity and conciseness, the other circumferential extent configurations discussed herein are illustrated with regard to wave washers having circumferential extents that

are ring-shaped (as opposed to spiral-shaped) and thicker compared to the wave washer embodiments summarized above (as those summarized embodiments are illustrated), however it should be understood that the additional circumferential extent variations discussed herein can be applied individually or in various combinations to the spiral-shaped, concentric, and/or radially varying undulation amplitude configurations, without departing from the scope of the invention.

[0026] For example, a variety of circumferential extents are illustrated and discussed herein. In some embodiments, the circumferential extent is generally planar (e.g., the extent extends in a plane and all of the waves undulate perpendicular to that plane). In other embodiments, the circumferential extent is generally conical (e.g., the extent extends to define a conical surface concentric with the central bore and the waves undulate perpendicular to that surface at their respective positions on the surface) and radially straight, such that the height of the wave washer is linearly related to the radial width of the circumferential extent. In still other embodiments, the circumferential extent is generally semispherical (e.g., the extent extends to define a semispherical surface concentric with the central bore and the waves undulate perpendicular to that surface at their respective positions on the surface) and radially bowed, such that the height of the wave washer is not linearly related to the radial width of the circumferential extent (but rather the wave washer may, for example, be parabolic in shape). In still other embodiments, the circumferential extent extends radially downwardly from the central bore. In still other embodiments, the circumferential extent is doubled, with a lower portion extending radially downwardly from the central bore and an upper portion extending radially upwardly from the central bore. By changing the circumferential extent from a generally planar configuration to a generally conical or generally semispherical configuration, the resting height of the washer is increased and the radial expansion potential of the washer is increased while the structural integrity of the washer is enhanced. The shape and direction of the circumferential extent can be varied to accommodate desired applications, inasmuch as varying the dimensions will affect the behavior of the wave washer in expansion and retraction.

[0027] Also, for example, additional configurations of the circumferential extent are possible, and are illustrated and discussed herein, to affect the behavior of the wave washer in expansion and retraction. In some embodiments, in addition to the concentric waviness common to all of the wave washer embodiments, the

circumferential extent has at least one concentric or radial characteristic that alters the performance of the wave washer in expansion and/or retraction. More specifically, in some embodiments, the circumferential extent is not only concentrically wavy, but is also radially wavy. In other embodiments, the circumferential extent is radially thinning (the portion of the extent near the central bore is thicker than the portion of the extent near the outer edge of the washer). In still other embodiments, the circumferential extent is radially thickening (the portion of the extent near the central bore is thinner than the portion of the extent near the outer edge of the washer). In still other embodiments, the circumferential extent is concentrically grooved, having grooves that are similarly dimensioned to one another regardless of their relative radial distance from the central bore, or grooves that vary in dimension from one another depending on their relative radial distance from the central bore. These alterations, depending on the configuration, cause certain portions (e.g., grooved, thinner, or more wavy portions) of the circumferential extent to expand more readily than other portions (e.g., non-grooved, thicker or less wavy portions).

[0028] It should be noted that with regard to the waves of the wave washers of the invention, one or both of the depth and the width of each wave can be (1) decreasing along the length of the wave from the outer edge of the washer toward the central bore, (2) increasing along the length of the wave from the outer edge of the washer toward the central bore, (3) uniform along the length of the wave from the outer edge of the washer toward the central bore, or (4) varied along the length of each wave from the outer edge of the washer toward the central bore, either randomly or according to a pattern. Moreover, it can be the case that each wave is not formed similarly to one or more other waves, but rather one or more waves are formed in any of the above-mentioned fashions, while one or more other waves are formed in another of the above-mentioned fashions or other fashions. It should be clear that any wave pattern can be implemented without departing from the scope of the invention. By making the wave pattern non-uniform, certain portions of the circumferential extent give more readily than other portions, and therefore the behavior of the wave washer in expansion and retraction can be modified and/or controlled.

[0029] For disposing the wave washer (whichever wave washer embodiment is chosen for the clinical application) between the plates, each wave washer embodiment has at least one feature suitable for this purpose, and the plates of the

artificial disc comprise cooperating features suitable for this purpose. With regard to the wave washer features, each wave washer embodiment has a central bore and at least one end that expands and retracts as described above. The central bore of some wave washer embodiments forms a curvate socket on a narrow end of the wave washer, for coupling with a ball-shaped protuberance on a plate as described below.

[0030] With regard to the structure and coupling features of the plates, three plate embodiments are illustrated and described herein, although other suitable plate embodiments can be used with the invention. Each of the three plate embodiments has the above described convex mesh on its outwardly facing surface, although other vertebral body attachment devices and mechanisms can be used without departing from the scope of the invention. Each of the three plate embodiments has a different inwardly facing surface from the other two plate embodiments. The first plate embodiment has a flat inwardly facing surface that accepts a fastener (e.g., a screw, plug, dowel or rivet; a rivet is used herein as an example) for rotatably securing thereto a narrow end of a wave washer having a circumferential extent that is generally conical or generally semispherical, and/or that accepts a flanged (and preferably rotatable) fastener (e.g., a screw, plug, dowel, rivet, or spoked post; a rotatable spoked post is used herein as an example) for securing thereto a wave washer having a circumferential extent that is generally planar. The second plate embodiment has a circular recess on its inwardly facing surface, for rotationally housing an end of a wave washer and allowing the end to expand in unrestricted fashion when the wave washer is compressed. The third plate embodiment has a semispherical (e.g., ball-shaped) protuberance on its inwardly facing surface, for rotatably and angulatably holding a narrow end of a wave washer, which narrow end includes a curvate socket as described below.

[0031] The semispherical protuberance has an axial bore that receives a deflection preventing element (e.g., a rivet, plug, dowel, or screw; a rivet is used herein as an example). Prior to the insertion of the rivet, the ball-shaped protuberance can deflect radially inward (so that the ball-shaped protuberance contracts). The insertion of the rivet eliminates the capacity for this deflection. The curvate socket, having a substantially constant radius of curvature that is also substantially equivalent to the radius of the ball-shaped protuberance, accommodates the ball-shaped protuberance for free rotation and angulation once the ball-shaped protuberance is disposed in the curvate socket, but in the ball-shaped protuberance's

undeflected state, the ball-shaped protuberance cannot fit through the opening leading to the curvate socket. Therefore, the deflectability of the ball-shaped protuberance, prior to the insertion of the rivet, permits the ball-shaped protuberance to be inserted into the curvate socket. Subsequent introduction of the rivet into the axial bore of the ball-shaped protuberance prevents the ball-shaped protuberance from deflecting, and thus prevents the ball-shaped protuberance from escaping the socket. Thereby, the ball-shaped protuberance can be secured in the curvate socket so that it rotates and angulates therein through a range of angles, thus permitting the plates to rotate and angulate relative to one another through a corresponding range of angles equivalent to the fraction of normal human spine rotation and angulation (to mimic normal disc rotation and angulation).

[0032] With the three plate embodiments, the various wave washer embodiments, and the several manners in which they may be coupled together, it is possible to assemble a variety of artificial disc embodiments. Many examples are described herein, although many permutations that are contemplated and encompassed by the invention are not specifically identified herein, but are readily identifiable with an understanding of the invention as described. For example, any of the wave washers can be disposed between circular recesses of opposing plates. Also for example, all wave washers having a curvate socket can have the curvate socket coupled with a ball-shaped protuberance on a plate. Also for example, all wave washers having a simple bore (i.e., without a curvate socket) can have the simple bore coupled with a flat inwardly facing surface of a plate using a fastener (e.g., a rotatable spoked post or a screw or a rivet). Also for example, each wave washer having a wide end (e.g., wave washers having a circumferential extent that is generally conical or generally semispherical) can be disposed with its wide end in a circular recess of a plate, and a retaining element (e.g., a shield) can be secured over the wave washer after it has been placed in the circular recess to prevent the wave washer from escaping the recess when a tension load is applied to the plates.

[0033] Each assembly enjoys spring-like performance with respect to axial compressive loads, as well as long cycle life to mimic the axial biomechanical performance of the normal human intervertebral disc. The wave washer expands radially and/or circumferentially under a compressive load, only to spring back into its undeflected shape when it is unloaded. As the wave washer compresses and decompresses, the walls of the circular recess of the second plate embodiment

maintain the end of the wave washer within a prescribed boundary on the inwardly facing surface of the plate. Certain assemblies withstand tension loads on the outwardly facing surfaces, because (in embodiments having a generally conical or generally semispherical extent) the shield retains the wide end in the circular recess and because (in embodiments using the ball-shaped protuberance) the rivet in the axial bore prevents the ball-shaped protuberance from deflecting, thus preventing it from exiting the curvate socket and because (in embodiments in which the narrow end of a wave washer is secured by a rivet or a rotatable spoked post), the flanged portion of the rivet (or the spokes of the post) prevents the wave washer from escaping the circular recess. Accordingly, in such embodiments, once the plates are secured to the vertebral bones, the assembly will not come apart when a normally experienced tension load is applied to the spine, similar to the tension-bearing integrity of a healthy natural intervertebral disc.

[0034] Assemblies having the ball-and-socket joint also provide a centroid of motion centrally located within the intervertebral space, because the plates are made rotatable and angulatable relative to one another by the ball-shaped protuberance being rotatably and angulatably coupled in the curvate socket. The centroid of motion remains in the ball-shaped protuberance, and thus remains centrally located between the vertebral bodies, similar to the centroid of motion in a healthy natural intervertebral disc.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Figures 1.1 through 1.7 show various embodiments of plates of the invention for use in an artificial disc of the invention.

[0036] Figures 1.1 and 1.2 show a bottom plan view and a side cutaway view, respectively, of a plate having a flat surface on its inwardly facing surface.

[0037] Figures 1.3 and 1.4 show a bottom plan view and a side cutaway view, respectively, of a plate having a circular recess on its inwardly facing surface.

[0038] Figures 1.5 and 1.6 show a bottom plan view and a side cutaway view, respectively, of a plate having a ball-shaped protuberance on its inwardly facing surface.

[0039] Figure 1.7 shows a top plan view of any of the plates of Figures 1.1 through 1.6 (all appear the same from this view).

[0040] Figures 2.1 through 2.6 show top views of various embodiments of

wave washers of the invention for use in an artificial disc of the invention, to illustrate a variety of circumferential extent configurations and central bore configurations contemplated by the invention.

5 [0041] Figure 2.1 shows a wave washer having a continuous circumferential extent.

[0042] Figure 2.2 shows a wave washer having a circumferential extent with radially extending slots.

[0043] Figure 2.3 shows a wave washer having a circumferential extent with radially extending and spiraling slots.

10 [0044] Figure 2.4 shows a wave washer having a continuous circumferential extent and a curvate socket.

[0045] Figure 2.5 shows a wave washer having a circumferential extent with radially extending slots and a curvate socket.

15 [0046] Figure 2.6 shows a wave washer having a circumferential extent with radially extending and spiraling slots and a curvate socket.

[0047] Figures 3.1 through 3.14 show side cross-section views and side views of various embodiments of wave washers of the invention for use in an artificial disc of the invention, to illustrate additional varieties of circumferential extent configurations and central bore configurations of the invention.

20 [0048] Figures 3.1 and 3.8 show wave washers having a generally planar circumferential extent.

[0049] Figures 3.2 and 3.9 show wave washers having a generally conical and radially straight circumferential extent.

25 [0050] Figures 3.3 and 3.10 show wave washers having a generally semispherical and radially bowed circumferential extent.

[0051] Figures 3.4 and 3.11 show wave washers having a generally conical and radially straight circumferential extent that has a lower downwardly extending portion and an upper upwardly extending portion.

30 [0052] Figures 3.5 and 3.12 show wave washers having a generally semispherical and radially bowed circumferential extent that has a lower downwardly extending portion and an upper upwardly extending portion.

[0053] Figures 3.6 and 3.13 show wave washers having a generally conical and radially straight circumferential extent and a curvate socket.

[0054] Figures 3.7 and 3.14 show wave washers having a generally

semispherical and radially bowed circumferential extent and a curvate socket.

[0055] Figures 4.1 through 4.15 show side cross-section views and top views of circumferential extents of various embodiments of wave washers, to illustrate additional varieties of circumferential extent configurations of the invention.

5 [0056] Figure 4.1 shows a generally straight circumferential extent that is radially wavy.

[0057] Figure 4.2 shows a generally straight circumferential extent that is radially thinning.

10 [0058] Figure 4.3 shows a generally straight circumferential extent that is radially thickening.

[0059] Figure 4.4 shows a generally straight circumferential extent that is concentrically grooved, with grooves that are similarly dimensioned to one another regardless of their relative radial distance from the central hub.

15 [0060] Figure 4.5 shows a generally straight circumferential extent that is concentrically grooved, with grooves that become smaller with a greater radial distance of the groove from the central hub.

[0061] Figure 4.6 shows a generally straight circumferential extent that is concentrically grooved, with grooves that become larger with a greater radial distance of the groove from the central hub.

20 [0062] Figure 4.7 shows a generally bowed circumferential extent that is radially wavy.

[0063] Figure 4.8 shows a generally bowed circumferential extent that is radially thinning.

25 [0064] Figure 4.9 shows a generally bowed circumferential extent that is radially thickening.

[0065] Figure 4.10 shows a generally bowed circumferential extent that is concentrically grooved, with grooves that are similarly dimensioned to one another regardless of their relative radial distance from the central hub.

30 [0066] Figure 4.11 shows a generally bowed circumferential extent that is concentrically grooved, with grooves that become smaller with a greater radial distance of the groove from the central hub.

[0067] Figure 4.12 shows a generally bowed circumferential extent that is concentrically grooved, with grooves that become larger with a greater radial distance of the groove from the central hub.

[0068] Figure 4.13 shows a wave washer having a circumferential extent with concentric grooves having a concentrically varying width.

[0069] Figures 4.14 and 4.15 show a wave washer having a circumferential extent with at least one wave that varies in width and depth along the length of the wave.

[0070] Figures 5.1 through 5.6 show side views of various assembled artificial disc embodiments of the invention, with plates and shields of the invention in side cutaway view, but wave washers of the invention in side view.

[0071] Figure 5.1 shows a wave washer having a generally planar circumferential extent, disposed between circular recesses of opposing plates.

[0072] Figure 5.2 shows a wave washer having a generally planar circumferential extent, disposed between circular recesses of opposing plates and maintained within the circular recesses by rotatable spoked posts.

[0073] Figure 5.3 shows a wave washer having a generally semispherical circumferential extent, disposed between circular recesses of opposing plates.

[0074] Figure 5.4 shows a wave washer having a generally semispherical circumferential extent, rotatably secured by a flanged rivet to a flat surface of an upper plate and its wide end seated within a circular recess of a lower plate.

[0075] Figure 5.5 shows a wave washer having a generally semispherical circumferential extent and a curvate socket, with its curvate socket coupled to a ball-shaped protuberance of an upper plate and its wide end seated within a circular recess of a lower plate.

[0076] Figure 5.6 shows a wave washer having two wide ends, with its top wide end seated within a circular recess of an upper plate, and its bottom wide end seated within a circular recess of a lower plate.

[0077] Figure 6.1 through 6.5 show perspective views of additional wave washers of the invention, to illustrate additional varieties of circumferential extent configurations of the invention.

[0078] Figure 6.1 shows a wave washer having a ring-shaped circumferential extent and a radial slot extending fully through the circumferential extent.

[0079] Figure 6.2 shows a wave washer having a spiral-shaped circumferential extent.

[0080] Figure 6.3 shows a plurality of concentrically disposed wave washers, each having a continuous circumferential extent.

[0081] Figure 6.4 shows a wave washer having a spiral-shaped circumferential extent that has peaks and valleys of radially diminishing amplitude.

[0082] Figure 6.5 shows a plurality of concentrically disposed wave washers, each having a continuous circumferential extent, disposed such that wave washers
5 having peaks and valley of greater amplitude are radially close to the center of the plurality.

[0083] Figure 7 shows a side perspective view of a prior art interbody fusion device.

[0084] Figure 8 shows a front view of the anterior portion of the lumbo-sacral
10 region of a human spine, into which a pair of interbody fusion devices of Figure 7 have been implanted.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0085] While the invention will be described more fully hereinafter with reference to the accompanying drawings, in which particular embodiments and methods of implantation are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of the invention. Accordingly, the descriptions that follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the invention and not as limiting of such broad scope. Like numbers refer to similar features of like elements throughout.

[0086] Referring now to Figures 1.1 through 1.7, various embodiments of plates of the invention for use in an artificial disc of the invention are shown in bottom plan views (Figures 1.1, 1.3, and 1.5), side cutaway views (where cross-sectional areas and surfaces viewable behind them are shown) (Figures 1.2, 1.4, and 1.6), and a top plan view (Figure 1.7). More specifically, Figures 1.1 and 1.2 show a bottom plan view and a side cutaway view, respectively, of a first embodiment 100a of a plate. Figures 1.3 and 1.4 show a bottom plan view and a side cutaway view, respectively, of a second embodiment 100b of a plate. Figures 1.5 and 1.6 show a bottom plan view and a side cutaway view, respectively, of a third embodiment 100c of a plate. Figure 1.7 shows a top plan view of any of the plates 100a-c (all appear the same from this view). As will be described in greater detail below, depending on the type of wave washer used in a particular embodiment of an artificial disc of the invention, two plates selected (for the manner in which they cooperate with the type of wave washer used in the embodiment) from these three embodiments will be used as opposing plates of the embodiment. Some embodiments of the artificial disc use two plates of the same plate embodiment.

[0087] Each plate 100a-c has an exterior surface 108a-c. Because the artificial disc of the invention is to be positioned between the facing surfaces of adjacent vertebral bodies, the two plates used in the artificial disc are disposed such that the exterior surfaces face away from one another (as best seen in Figures 5.1 through 5.6, discussed below). The two plates are to mate with the vertebral bodies so as to not rotate relative thereto, but rather to permit the spinal segments to axially compress and bend relative to one another in manners that mimic the natural motion of the spinal segment. This motion is permitted by the performance of a wave washer

(described below) disposed between the secured plates. The mating of the plates to the vertebral bodies and the application of the wave washer to the plates are described below.

[0088] More particularly, each plate 100a-c is a flat plate (preferably made of a metal such as, for example, titanium) having an overall shape that conforms to the overall shape of the respective endplate of the vertebral body with which it is to mate. Further, each plate 100a-c comprises a vertebral body contact element (e.g., a convex mesh 106a-c) (preferably oval in shape) that is attached to the exterior surface 108a-c of the plate 100a-c to provide a vertebral body contact surface. The mesh 106a-c is secured at its perimeter, by laser welds, to the exterior surface 108a-c of the plate 100a-c. The mesh is domed in its initial undeflected conformation, but deflects as necessary during insertion of the artificial disc between vertebral bodies, and, once the artificial disc is seated between the vertebral bodies, deforms as necessary under anatomical loads to reshape itself to the concave surface of the vertebral endplate. This affords the plate having the mesh substantially superior gripping and holding strength upon initial implantation as compared with other artificial disc products. The mesh further provides an osteoconductive surface through which the bone may ultimately grow. The mesh is preferably comprised of titanium, but can also be formed from other metals and/or non-metals without departing from the scope of the invention.

[0089] Each plate 100a-c further comprises at least a lateral ring 110a-c that is osteoconductive, which may be, for example, a sprayed deposition layer, or an adhesive applied beaded metal layer, or another suitable porous coating. This porous ring permits the long-term ingrowth of vertebral bone into the plate, thus permanently securing the prosthesis within the intervertebral space. It shall be understood that this porous layer 110a-c may extend beneath the domed mesh 106a-c as well, but is more importantly applied to the lateral rim of the exterior surface 108a-c of the plate 100a-c that seats directly against the vertebral body.

[0090] It should be understood that the convex mesh attachment devices and methods described herein can be used not only with the artificial discs and artificial disc plates described or referred to herein, but also with other artificial discs and artificial disc plates, including, but not limited to, those currently known in the art. Therefore, the description of the mesh attachment devices and methods being used with the artificial discs and artificial disc plates described or referred to herein should

not be construed as limiting the application and/or usefulness of the mesh attachment device.

[0091] With regard to the disposition of a wave washer between two plates, each of the plates 100a-c comprises features for applying the wave washer thereto, and the various application methods are described below. More specifically, the first plate embodiment 100a includes an inwardly facing surface 104a that includes a flat surface 102a that accepts a fastener (e.g., a screw, plug, dowel or rivet; a rivet 114a is used herein as an example) (shown in Figure 5.4) for rotatably securing a narrow end of a wave washer thereto.

[0092] The second plate embodiment 100b includes an inwardly facing surface 104b that includes a circular recess 102b for rotationally housing an end of a wave washer and allowing the end to expand in unrestricted fashion when the wave washer is compressed, and the inwardly facing surface 104b also accepts fasteners (e.g., screw, plugs, dowels, or rivets; rivets 116b are used herein as examples) (shown in Figures 5.4 through 5.6) for securing a retaining element (e.g., a shield 118b) (the purpose and application of the shield are described below and shown on Figures 5.4 through 5.6).

[0093] The third plate embodiment 100c includes an inwardly facing surface 104c that includes an inwardly directed semispherical (e.g., ball-shaped) protuberance 102c. The ball-shaped protuberance 102c includes a series of slots 120c that render the ball-shaped protuberance 102c radially compressible and expandable in correspondence with a radial pressure (or a radial component of a pressure applied thereto). The ball-shaped protuberance 102c further includes an axial bore 122c that accepts a deflection preventing element (e.g., a screw, plug, dowel, or rivet; a rivet 124c is used herein as an example) (shown in Figure 5.5). (If a screw is used, the axial bore can be threaded to accept it.) Prior to the insertion of the rivet 124c, the ball-shaped protuberance 102c can deflect radially inward because the slots 120c will narrow under a radial pressure. The insertion of the rivet 124c eliminates the capacity for this deflection. Therefore, the ball-shaped protuberance 102c, before receiving the rivet 124c, can be compressed to seat in a curvate socket of a wave washer and, once the ball-shaped protuberance 102c has been seated in the curvate socket, the rivet 124c can be inserted into the axial bore 122c to ensure that the ball-shaped protuberance 102c remains held in the curvate socket. A hole can be provided in the opposing plate so that the interior of the device may be readily accessed if a need

should arise.

[0094] The curvate socket has a substantially constant radius of curvature that is also substantially equivalent to the radius of the ball-shaped protuberance with which it mates, so that when the ball-shaped protuberance is secured therein, the ball-shaped protuberance can rotate and angulate freely relative to the curvate socket through a range of angles, thus permitting the opposing plates to rotate and angulate freely relative to one another through a corresponding range of angles equivalent to the fraction of normal human spine rotation and angulation (to mimic normal disc rotation and angulation). It should be understood that the specific dimensions of the ball-shaped protuberance, the mechanism for radial compressibility of the ball-shaped protuberance, and the mechanism for preventing radial compression of the ball-shaped protuberance are not limited to those shown, but rather can be varied and changed without departing from the scope of the invention.

[0095] Referring now to Figure 6.1, an embodiment of a wave washer force restoring element of the invention is provided in a perspective view. The wave washer 610 comprises an undulating ring-shaped circumferential extent 615 (preferably formed from a titanium alloy or stainless steel) having a radial slot 612 that extends fully through the circumferential extent. The circumferential extent 615, while maintaining a constant radius, has undulations (a sinusoidal-type rising and falling of the extent) that create periodic peaks 613 and valleys 611.

[0096] It shall be understood that the wave washer 610 can also be provided without a radial break or slot 612, and would thus be continuous. The restoring force of a wave washer (whether continuous or slotted) is proportional to the elastic properties of the material, and these are opposed as the compressive load is applied down onto the peaks 613 and up against the valleys 611. In the case of a continuous wave washer, the loads are translated into hoop stresses that apply stresses directed toward radially expanding the washer. In the case of the radially slotted washer 610, the radial slot 612 permits the compressive load that is applied to the washer (again, down onto the peaks 613 and up against the valleys 611) to cause the washer to radially expand without the build-up of hoop stresses. If the slotted wave washer 610 is radially constrained against such an expansion, the slot 612 is able to close. The wave washer is therefore able to deflect downwardly without radially expanding. Stated equivalently, a difference between the radially slotted wave washer 610 of Figure 6.1, and a continuous wave washer, is that the continuous wave washer

responds to a compressive load by deflecting radially (with a very high stress to deflection ratio), whereas the radially slotted wave washer 610, when radially constrained, deflects circumferentially, closing the slot 612 (which is characteristic of a much lower stress to deflection ratio).

5 [0097] With reference now to Figure 6.2, another embodiment of a wave washer force restoring element of the invention is provided in perspective view. The wave washer 620 comprises a circumferential extent 625 formed from a spirally wound band of material (as above, a suitable titanium alloy or stainless steel is preferable). As with the ring-shaped wave washer 610 introduced above, the spirally

10 wound wave washer 620 includes a series of alternating and undulating peaks 623 and valleys 621 that extend continuously around the spiral. The spiral wave washer 620 in Figure 6.2 shows the series of peaks 623 and valleys 621 being radially aligned. Alternatively, it shall be understood that the peaks and valleys may be non-aligned.

[0098] With reference to Figure 6.3, yet another embodiment of a wave

15 washer force restoring element of the invention is provided in perspective view. A plurality of wave washers 630a-c each comprises a circumferential extent 635a-c that is ring-shaped, similar to the wave washer 610 introduced above, but continuous (i.e., it has no radial slot). The wave washers 630a-c are disposed relative to one another so that they are concentric, with the wave washer 630a having the smallest radius

20 being surrounded by the wave washer 630b having the next largest radius, which is in turn surrounded by a wave washer 630c having an even larger radius. The plurality of wave washers 630a-c therefore provides a functionality similar to the spirally wound wave washer 620 introduced above. It should be understood that more or fewer concentric wave washers can be similarly disposed without departing from the

25 scope of the invention. Further, although the peaks 633a-c and valleys 631a-c of the wave washers 630a-c are radially aligned, it shall be understood that alternatively, the peaks and valleys may be radially non-aligned in some embodiments.

[0099] With reference now to Figure 6.4, still another embodiment of a wave washer force restoring element of the invention is provided in perspective view. The

30 wave washer 640 comprises a circumferential extent 645 that is spirally wound, similar to the wave washer 620 introduced above, but in which the amplitudes of the peaks 643 and valleys 641 are radially diminishing. This conformation permits a non-linear load-deflection profile that more closely mimics the load-deflection performance of a natural disc. The spiral wave washer 640 in Figure 6.4 shows the series of peaks 643

and valleys 641 being radially non-aligned. Alternatively, it shall be understood that the peaks and valleys may be radially aligned.

[00100] With reference to Figure 6.5, yet another embodiment of a wave washer force restoring element of the invention is provided in perspective view. A plurality of wave washers 650a-c, formed and disposed similarly to the plurality of wave washers 650a-c introduced above in that each comprises a continuous circumferential extent 655a-c that is ring-shaped, and in that they are disposed relative to one another so that they are concentric, with the wave washer 650a having the smallest radius being surrounded by the wave washer 650b having the next largest radius, which is in turn surrounded by a wave washer 650c having an even larger radius. However, in this embodiment, the inner wave washer 650a has peaks 653a and valleys 651a with amplitudes smaller than the amplitudes of the peaks 653b and valleys 651b of the middle wave washer 650b, which in turn have amplitudes smaller than the amplitudes of the peaks 653c and valleys 651c of the outer wave washer 650c. That is, the amplitudes of the peaks and valleys of the group of wave washers 650a-c decrease with the greater radial distance of the washer from the inner washer. The plurality of wave washers 650a-c therefore provides a functionality similar to the spirally wound wave washer 640 introduced above. It should be understood that more or fewer concentric wave washers can be similarly disposed without departing from the scope of the invention. Further, although the peaks 653a-c and valleys 651a-c of the wave washers 650a-c are radially aligned, it shall be understood that alternatively, the peaks and valleys may be radially non-aligned in some embodiments.

[00101] With regard to additional wave washer embodiments, changing the configuration of the circumferential extent in other ways modifies the magnitude of the compressive load support and restoring force provided by the wave washer. For clarity and conciseness, the other circumferential extent configurations discussed hereinbelow are illustrated with regard to wave washers having circumferential extents that are ring-shaped (as opposed to spiral-shaped) and thicker compared to the wave washer embodiments summarized above (as those summarized embodiments are illustrated), however it should be understood that the additional circumferential extent variations discussed herein can be applied individually or in various combinations to the spiral-shaped, concentric, and/or radially decreasing undulation amplitude configurations, without departing from the scope of the

invention.

[00102] Referring now to Figures 2.1 through 2.6, top views of various additional embodiments of wave washers of the invention for use in an artificial disc of the invention are shown to illustrate a variety of additional wave washer configurations and central bore configurations that are merely a subset of the wave washer configurations and central bore configurations contemplated by the invention. More specifically, each wave washer (e.g., 200a-u) has a circumferential extent (e.g., 202a-u) surrounding a central bore (e.g., 206a-u). The circumferential extent is concentrically wavy, such that the extent undulates along a concentric path around the central bore to form radially extending valleys (e.g., 208a-g) and peaks (e.g., 210a-g) (best shown by examples on Figures 3.8 through 3.14, discussed below) while preferably maintaining a constant radius. In some embodiments (e.g., 200a-g), the circumferential extent (e.g., 202a-g) is continuous (i.e., has no slots). In other embodiments (e.g., 200h-n), the circumferential extent (e.g., 202h-n) has radially extending slots (e.g., 212h-n). In still other embodiments (e.g., 200o-u), the circumferential extent (e.g., 202o-u) has radially extending and spiraling slots (e.g., 212o-u). The frequency, amplitude, and configuration of the waves and/or the number and configuration of the slots can be varied to accommodate any desired application, inasmuch as varying the dimensions will affect the behavior of the wave washer in expansion and retraction.

[00103] The restoring force of a wave washer is proportional to the elastic properties of the material. As a compressive load is applied to the wave washer, the forces are directed down onto the peaks and up against the valleys. A significant fraction of these forces are immediately translated into hoop stresses that apply stresses directly toward radially expanding the wave washer. This hoop stress is also counterbalanced by the material strength of the wave washer. The strain of the material causes a deflection in the height of the washer and a slight radial expansion. The slots in the slotted embodiments permit the compressive load that is applied to the wave washer down onto the peaks and up against the valleys to cause the wave washer to deflect such that the slots close. Thus, a difference between a slotted washer and a continuous washer is that the continuous washer responds to a compressive load by primarily deflecting radially (with a very high stress to deflection ratio), whereas the slotted washer deflects primarily circumferentially, closing the slots (which is characteristic of a much lower stress to deflection ratio).

Stated equivalently, a wave washer responds to a compressive load by deflecting compressively and either radially or circumferentially. With at least one slot formed in the washer, it expands and retracts far more elastically than a continuous washer. It should be understood that wave washers other than those shown are contemplated by the invention, including but not limited to wave washers having a circumferential extent that does not have a uniformly wide radius.

[00104] With regard to the central bore configurations 206a-u shown on Figures 2.1 through 2.6, these are discussed in greater detail below with reference to Figures 5.1 through 5.6 regarding methods of applying the wave washers to the plates discussed above. However, for properly understanding the discussions of Figures 3.1 through 3.14 and 4.1 through 4.15 below, it is important to summarize here that some wave washer embodiments (e.g., 200a-e,h-l,o-s) have a simple bore (e.g., 206a-e,h-l,o-s), and other wave washer embodiments (e.g., 200f-g,m-n,t-u) have a bore that forms a curvate socket (e.g., 206f-g,m-n,t-u) of a type described above with regard to being mateable with the semispherical protuberance described above.

[00105] Referring now also to Figures 3.1 through 3.14, side cross-section views (where only the cross-sectional area is shown) and corresponding side views (some with side cross-section views shown in phantom for clarity) of various embodiments of wave washers are shown to illustrate additional varieties of wave washer configurations and central bore configurations that are merely a subset of the wave washer configurations and central bore configurations contemplated by the invention. The side cross-sections are taken along cut lines A1-A1', F1-F1', H-H', M-M', O-O', and T-T' on Figures 2.1 through 2.6, as applicable, and the side views are taken along cut lines A2-A2' and F2-F2' on Figures 2.1 and 2.4, as applicable.

[00106] It should be understood that the use of multiple reference numbers for various elements are used throughout the figures to indicate where a single view illustrates more than one wave washer embodiment, given that some wave washers look similar from certain views but not similar from other views. This has been done to consolidate illustrations for conciseness and clarity. For example, Figures 3.1 through 3.5 illustrate wave washer embodiments that from a top view appear as any of Figures 2.1 through 2.3. Also, for example, Figures 3.6 and 3.7 illustrate wave washer embodiments that from a top view appear as any one of Figures 2.4 through 2.6. Stated alternatively, each of Figures 3.1 through 3.7 is not a side cross-section view that is associated with only one of the top views of Figures 2.1 through 2.6, but

rather is associatable with more than one of the top views of Figures 2.1 through 2.6. And, for example, Figures 3.8 through 3.12 are side views corresponding respectively to the side cross-section views of Figures 3.1 through 3.5, but only with regard to certain wave washer embodiments (e.g., 200a-e), as noted by reference numbers, and

5 Figures 3.13 and 3.14 are side views corresponding respectively to the side cross-section views of Figures 3.6 and 3.7, but only with regard to certain wave washer embodiments (e.g., 200f-g), as noted by reference numbers. It should be understood, however, that certain configurations of wave washer embodiments (e.g., 200h-l,o-s) would have similar side view appearances as Figure 3.8 through 3.12, and that certain

10 configurations of wave washer embodiments (e.g., 200m-n,t-u) would have similar side view appearances as Figure 3.13 through 3.14, except for the presentation of straight or spiral slots, as applicable.

[00107] More specifically, Figure 3.1 shows a configuration where the circumferential extent of the wave washer (e.g., 200a,h,o) is generally planar (e.g., the extent extends in a plane and all of the waves undulate perpendicular to that plane).

15 Figures 3.2, 3.4, and 3.6 show configurations where the circumferential extent of the wave washer (e.g., 200b,d,f,i,k,m,p,r,t) is generally conical (e.g., the extent extends to define a conical surface concentric with the central bore and the waves undulate perpendicular to that surface at their respective positions on the surface) and radially straight, such that the height of the wave washer is linearly related to the radial width of the circumferential extent. Figures 3.3, 3.5, and 3.7 show configurations where the circumferential extent of the wave washer (e.g., 200c,e,g,j,l,n,q,s,u) is generally semispherical (e.g., the extent extends to define a semispherical surface concentric with the central bore and the waves undulate perpendicular to that surface at their

20 respective positions on the surface) and radially bowed, such that the height of the wave washer is not linearly related to the radial width of the circumferential extent (but rather the wave washer may, for example, be parabolic in shape). Figures 3.2, 3.3, 3.6 and 3.7 show configurations in which the circumferential extent of the wave washer (e.g., 200b,c,f,g,i,j,m,n,p,q,t,u) extends radially downwardly from the central bore. Figures 3.4 and 3.5 show configurations in which the circumferential extent of the wave washer (e.g., 200d,e,k,l,r,s) is doubled, with a lower portion extending radially downwardly from the central bore and an upper portion extending radially upwardly from the central bore.

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[00108] Further with regard to the central bores shown in top views on Figures

2.1 through 2.6, these are shown in side cross-section views in Figures 3.1 through 3.7, with some also shown in side cross-section views in phantom in Figures 3.13 and 3.14. More specifically, simple bores (e.g., 206a-e, h-l, o-s) are shown in side cross-section views in Figures 3.1 through 3.5. Bores that form curvate sockets (e.g., 206f-g, m-n, t-u) are shown in side cross-section views in Figures 3.6 and 3.7 and some of those (e.g., 206f-g) are also shown in side cross-section views in phantom in Figures 3.13 and 3.14.

[00109] Referring now also to Figures 4.1 through 4.12, side cross-section views (where only the cross-sectional area is shown) of circumferential extents (e.g., 202aa-ll) of various embodiments of wave washers are shown to illustrate additional varieties of wave washer configurations that are merely a subset of the wave washer configurations contemplated by the invention. The side cross-sections are taken from the inner edge of the circumferential extent (i.e., the edge of the central bore of the wave washer) radially to the outer edge of the circumferential extent. It should be understood that with regard to the remaining structure of the wave washers having the illustrated circumferential extents, the wave washers can share all or some of the features (e.g., bore configurations, double extent configurations, slot configurations, etc.) of the other wave washer embodiments discussed herein, and/or have features that are different and/or configured differently.

[00110] More specifically, Figures 4.1 through 4.12 show configurations where the circumferential extent of the wave washer is generally conical (Figures 4.1 through 4.6) (the waves undulate about a conical surface concentric with the central bore) and radially straight, such that the height of the wave washer is linearly related to the radial width of the circumferential extent, or generally semispherical (Figures 4.7 through 4.12) (the waves undulate about a semispherical surface concentric with the central bore) and radially bowed, such that the height of the wave washer is not linearly related to the radial width of the circumferential extent, but additionally have at least one concentric or radial characteristic (in addition to the concentric waviness common to all of the wave washer embodiments) that alters the performance of the wave washer in expansion and/or retraction. For example, the circumferential extents in Figures 4.1 and 4.7 are not only concentrically wavy, but are also radially wavy. Also for example, the circumferential extents in Figures 4.2 and 4.8 are radially thinning (the portion of the extent near the central bore is thicker than the portion of the extent near the outer edge of the washer). Also for example, the circumferential

extents in Figures 4.3 and 4.9 are radially thickening (the portion of the extent near the central bore is thinner than the portion of the extent near the outer edge of the washer). Also for example, the circumferential extents in Figures 4.4, 4.5, 4.6, 4.10, 4.11 and 4.12 are concentrically grooved, having grooves that are similarly dimensioned to one another regardless of their relative radial distance from the central bore (Figures 4.4 and 4.10), or grooves that vary in dimension from one another depending on their relative radial distance from the central bore (Figures 4.5, 4.6, 4.11 and 4.12). For example, the width and depth of the grooves in Figure 4.5 and the grooves in Figure 4.11 become smaller with the greater radial distance of the groove from the central bore. And, for example, the width and depth of the grooves in Figure 4.6 and the grooves in Figure 4.12 become larger with the greater radial distance of the groove from the central bore.

[00111] In some embodiments, at least one dimension of a concentric groove (such as, for example, the width and/or depth) can be applied to vary concentrically across the circumferential extent. Figure 4.13 shows one example of a configuration where two concentric grooves 211v, 212v, each concentrically varying in width, are applied to the circumferential extent 202v of a wave washer 200v.

[00112] It should be noted that with regard to the waves of the wave washers of the invention, one or both of the depth and the width of each wave can be (1) decreasing along the length of the wave from the outer edge of the washer toward the central bore, (2) increasing along the length of the wave from the outer edge of the washer toward the central bore, (3) uniform along the length of the wave from the outer edge of the washer toward the central bore, or (4) varied along the length of each wave from the outer edge of the washer toward the central bore, either randomly or according to a pattern. A wave washer embodiment 200w having a circumferential extent 202w, as an example of case (1), is shown in top view in Figure 4.14 (with dashed lines identifying the tangents of the adjacent peaks that define the wave) and in circumferential extent side cutaway view in Figure 4.15 (taken along cut lines W-W' in Figure 4.14), where both the width and depth of a wave 213w vary along the length of the wave. Moreover, it can be the case that each wave is not formed similarly to one or more other waves, but rather one or more waves are formed in any of the above-mentioned fashions, while one or more other waves are formed in another of the above-mentioned fashions or other fashions. It should be clear that any wave pattern can be implemented without departing from the scope of

the invention.

[00113] It should be understood that the circumferential extents contemplated by the invention include, but are not limited to, those having only one concentric or radial characteristic at a time. The use of more than one concentric or radial characteristic per arm is contemplated, as well as the use of concentric and radial characteristics simultaneously. Further, it is contemplated that some wave washer embodiments will use only a radially straight circumferential extent, some wave washer embodiments will use only a radially bowed circumferential extent, and some wave washer embodiments that will use a circumferential extent that is radially straight in some portions and radially bowed in other portions.

[00114] Each of the wave washers is suitable for disposition between two opposing plates of the invention. As noted above, and as discussed in greater detail below, depending on the type of wave washer used in the particular embodiment of the artificial disc of the invention, the two plates are selected (for the manner in which they cooperate with the type of wave washer used in the embodiment) from the three plate embodiments, for use as opposing plates of the embodiment. Some embodiments of the artificial disc use two plates of the same plate embodiment. In each embodiment, the plates are made rotatable and angulatable relative to one another (to mimic the functionality of a healthy natural intervertebral disc) by having a wave washer between the plates, and/or by the manner in which the wave washer is secured to one or both of the plates. Further in each embodiment, the same couplings, and/or through the use of additional coupling elements (e.g., shields, rivets, and/or rotatable spoked posts), enable the artificial disc embodiments to withstand tension loading (to mimic the functionality of a healthy natural intervertebral disc). Further in embodiments having a wave washer, the wave washer enables the artificial disc embodiments to axially compress and axially restore (to mimic the functionality of a healthy natural intervertebral disc).

[00115] Referring now also to Figures 5.1 through 5.6, these figures show side views of various assembled artificial disc embodiments contemplated by the invention. The side views show the plates in side cutaway view, but the wave washers in side view (with primary cross-sections and couplings in phantom in some figures for clarity). It should be understood that the illustrated embodiments do not encompass all embodiments contemplated by the invention, but rather were selected for illustration purposes to show how the features of the various illustrated plate

embodiments cooperate with corresponding features of the various illustrated wave washer embodiments, when the wave washers are disposed between opposing plates of the invention. While only certain assembled artificial disc embodiments are shown, it should be understood that wave washers not shown but having like plate coupling features can be secured to cooperating plates in the manner illustrated, in various permutations and combinations, and the same have been withheld from illustration for purposes of conciseness and clarity only to avoid duplicative illustration that would visually reiterate that which can be understood from the descriptions and illustrations herein.

[00116] For example, any of the wave washers can be disposed between circular recesses on inwardly facing surfaces of opposing plates (e.g., the circular recess 102b on the inwardly facing surface 104b of plate 100b). Figures 5.1 and 5.2 illustrate this disposition with wave washers (e.g., 200a) having a circumferential extent that is generally planar (see, e.g., Figures 3.1 and 3.8). (It should be understood that any of the wave washer embodiments of Figures 6.1 through 6.5, and similar embodiments, can be substituted for the wave washer 200a in Figures 5.1 and 5.2 and be similarly disposed as shown and/or coupled as shown with plates having circular recesses on inwardly facing surfaces to form additional artificial disc embodiments not specifically illustrated.) Figure 5.3 illustrates this disposition with a wave washer (e.g., 200c) having a circumferential extent that is generally semispherical (see, e.g., Figures 3.3 and 3.10), although the same disposition can be made with a wave washer (e.g., 200b) having a circumferential extent that is generally conical (see, e.g., Figures 3.2 and 3.9). Figure 5.6 illustrates this disposition with a wave washer (e.g., 200e) having a doubled circumferential extent that forms two generally semispherical portions and opposing wide ends (see, e.g., Figures 3.5 and 3.12), although the same disposition can be made with a wave washer (e.g., 200d) having a doubled circumferential extent that forms two generally conical portions and opposing wide ends (see, e.g., Figures 3.4 and 3.11). In each of these assemblies, each end of the wave washer fits within a respective circular recess 102b with room to expand when the wave washer is under compression. Because the diameter of the circular recess is greater than the diameter of the wave washer, unrestrained rotation of the wave washer relative to the plate having the circular recess is enabled, and compressive loading of the artificial disc (and therefore the wave washer) results in an unrestrained deflection of the wave washer, both as necessary for proper anatomical

response. Further in each of these and similarly constructed assemblies, the plates are rotatable relative to one another because the ends of the wave washer can rotate with respect to the plate having the circular recess in which the end seats as indicated above. Further, the plates are angulatable relative to one another because the waves
5 of the wave washer can individually compress and restore, enabling one side of the circumferential extent to compress and restore as the plates angulate relative to one another, while other portions of the circumferential extent do not.

[00117] Additional components can be applied in these assemblies in order to prevent removal of the wave washer from the circular recess(es) when the artificial
10 disc is loaded in tension. As an initial matter, if rotation of a wave washer with respect to one of the plates is not desirable, a simple fastener (e.g., a screw, plug, dowel or rivet) can be used to secure the circumferential extent of the wave washer to a circular recess or a flat surface of an inwardly facing surface of a plate so that the wave washer can still compress and decompress, but cannot rotate with respect to the
15 plate to which it is attached. Alternatively, Figure 5.2 illustrates an example of how a wave washer (e.g., 200a) having a circumferential extent that is generally planar can be rotationally maintained between circular recesses. Opposing rotatable posts 114b (each having at least one spoke 113b extending laterally from an end of the post 114b) can be rotatably installed, one to each of the plates, so that the spokes align with the
20 peaks and valleys of the wave washer, and the post is rotatable with respect to the plate. More specifically, an upper spoked post is applied with its post portion through the bore and its spokes bearing under the peaks to capture the peaks between the spokes and the upper plate, and a lower spoked post is applied with its post portion through the bore and its spokes bearing over the valleys to capture the
25 peaks between the spokes and the lower plate. In this manner, the wave washer is held against both of the plates so that the assembly maintains its integrity under a tension load while still permitting the washer to compress. It should be understood that one or both of the spoked posts can alternatively or additionally be formed from multiple parts, in order to facilitate easy construction of the assembly. It should also
30 be understood that other flanged fasteners can be used instead of a spoked post.

[00118] With regard to preventing the removal of the wide ends of wave washers (e.g., 200b-g) having generally conical or generally semispherical circumferential extents from the circular recess(es) when the artificial disc is loaded in tension, Figures 5.4 through 5.6 illustrate a retaining element (e.g., a shield 118b) that

can be placed over the wave washer and secured by fasteners (e.g., screws, plugs, dowels, or rivets; rivets 116b are used herein as examples). The shield 118b can have a central hole 120b through which the curvate socket (discussed below with regard to Figure 5.5) and the ball-shaped protuberance (discussed below with regard to Figure 5.5) can pass to accommodate efficient assembly of the artificial disc. The shield 118b can alternatively or additionally be formed from multiple shield parts, which would be useful, for example, in embodiments where no part of the wave washer can pass through the central hole 120b (see, e.g., the embodiment of Figure 5.6, discussed below).

[00119] A wave washer that has a simple central bore (see, e.g., Figures 2.1 through 2.3) and a circumferential extent that is generally conical (see, e.g., Figures 3.2 and 3.9) or generally semispherical (see, e.g., Figures 3.3 and 3.10) can be disposed with its wide end against a circular recess on an inwardly facing surface of a plate (e.g., the circular recess 102b on the inwardly facing surface 104b of plate 100b) as described above, and its narrow end rotatably secured to a flat surface on an inwardly facing surface on an opposing plate (e.g., the flat surface 102a on the inwardly facing surface 104a of plate 100a). As shown in Figure 5.4, the narrow end of the wave washer (e.g., 200b-c) can be rotatably secured to the flat surface 104a with a flanged fastener (e.g., a flanged screw, plug, dowel or rivet; a flanged rivet 114a is used herein as an example) passing through the central bore of the wave washer and secured to the flat surface 104a of the plate 100a. The flanged rivet 114a has a flanged portion at the end of a post portion. The post portion has a diameter smaller than the diameter of the bore, and a length that is longer than the thickness of the wave washer extent surrounding the central bore, and the flanged portion has a diameter greater than the diameter of the bore. Therefore, upon application of the rivet 114a, the wave washer is secured to the plate 100a so that it can still rotate with respect to the plate 100a. (A threaded bore in the plate can also be used in conjunction with a similarly flanged screw to achieve the same functionality.) As also discussed above with regard to the securing of the wide end of the wave washer, the plates are secondarily rotatable relative to one another because the wide end of the wave washer can rotate with respect to the plate having the circular recess in which the wide end seats. Further, the plates are angulatable relative to one another because the waves of the wave washer can individually compress and restore, enabling one side of the circumferential extent to compress and restore as the plates angulate relative to one

another, while other portions of the circumferential extent do not.

[00120] A wave washer that has a central bore that forms a curvate socket (see, e.g., Figures 2.4 through 2.6) and a circumferential extent that is generally conical (see, e.g., Figures 3.6 and 3.13) or generally semispherical (see, e.g., Figures 3.7 and 3.14)

5 can be disposed with its wide end against a circular recess on an inwardly facing surface of a plate (e.g., the circular recess 102b on the inwardly facing surface 104b of plate 100b) as described above, and its narrow end rotatably and angulatably coupled with a semispherical protuberance on an inwardly facing surface on an opposing plate (e.g., the ball-shaped protuberance 102c on the inwardly facing surface 104c of plate 100c). As shown in Figure 5.5, the central bore of such a wave washer (e.g., 200f-g) preferably forms a curvate socket (e.g., 206f-g,m-n,t-u) within which the ball-shaped protuberance 102c is securable for free rotation and angulation through a range of angles. The structure of the curvate socket and the coupling of the ball-shaped protuberance with the curvate socket are as described above. As noted above, 15 a deflection preventing element (e.g., a screw, plug, dowel, or rivet 124c) applied to the axial bore 122c after the ball-shaped protuberance 102c has been inserted into the curvate socket prevents the deflection of the ball-shaped protuberance 102c so that it does not escape the curvate socket. The plates are rotatable relative to one another primarily because the ball-shaped protuberance rotates freely within the curvate socket, and secondarily because the wide end of the wave washer can rotate with 20 respect to the plate having the circular recess in which the wide end seats (discussed below). Also, the plates are angulatable relative to one another primarily because the ball-shaped protuberance angulates freely within the curvate socket, and secondarily because the waves of the wave washer can individually compress and restore, 25 enabling one side of the circumferential extents to compress and restore as the plates angulate relative to one another, while other portions of the circumferential extent do not.

[00121] In embodiments having a ball-and-socket joint as described above, because the ball-shaped protuberance is held within the curvate socket by a rivet in 30 the axial bore preventing radial compression of the ball-shaped protuberance, the artificial disc can withstand tension loading of the plates, as necessary for proper anatomical response. More particularly, when a tension load is applied to the plates, the ball-shaped protuberance in the curvate socket seeks to radially compress to fit through the opening of the curvate socket. However, the rivet in the axial bore of the

ball-shaped protuberance prevents the radial compression, thereby preventing the ball-shaped protuberance from exiting the curvate socket. Further, in embodiments that have a wave washer with a generally conical or generally semispherical circumferential extent, as the wide end of the wave washer seeks to escape the circular recess of the plate, the rivets holding the shield in place over the wave washer prevent the shield from separating from the plate when the wave washer presses against the inner surface of the shield. Further, in embodiments where the narrow end of the wave washer is rotatably secured against a plate by a rivet, the flanged portion of the rivet prevents the separation of the narrow end of the wave washer.

Therefore, the assembly does not come apart under normally experienced tension loads. This ensures that no individual parts of the assembly will pop out or slip out from between the vertebral bodies when the patient stretches or hangs while exercising or performing other activities. Thus, in combination with the securing of the plates to the adjacent vertebral bones via the mesh domes, the disc assembly has an integrity similar to the tension-bearing integrity of a healthy natural intervertebral disc.

[00122] Further, because the plates in some embodiments are made angulatable relative to one another by the ball-shaped protuberance being rotatably and angulatably coupled in a curvate socket, the disc assembly provides a centroid of motion within the ball-shaped protuberance. Accordingly, in those embodiments, the centroid of motion of the disc assembly remains centrally located between the vertebral bodies, similar to the centroid of motion in a healthy natural intervertebral disc.

[00123] While there has been described and illustrated specific embodiments of an artificial disc, it will be apparent to those skilled in the art that variations and modifications are possible without deviating from the broad spirit and principle of the invention. The invention, therefore, shall not be limited to the specific embodiments discussed herein.

CLAIMSWhat is claimed is:

- 5 1. An intervertebral spacer device, comprising:
 first and second plates, said plates being disposed in a spaced apart
relationship such that a plate surface of said first plate faces a plate surface of said
second plate, said facing surfaces being inner surfaces, and alternative faces of each
plate being outer surfaces; and
10 at least one restoring force providing element disposed between the inner
surfaces of said first and second plates, and disposed such that a compressive load
applied to the outer surfaces of said first and second plates is counteracted by said at
least one restoring force providing element, said at least one restoring force providing
element including at least one wave washer.
- 15 2. The intervertebral spacer device of claim 1, wherein the at least one
wave washer comprises a plurality of wave washers.
3. The intervertebral spacer device of claim 1, wherein the at least one
20 wave washer has a circumferential extent having at least one slot.
4. The intervertebral spacer device of claim 3, wherein the at least one
slot comprises at least one radially extending slot.
- 25 5. The intervertebral spacer device of claim 3, wherein the at least one
slot comprises at least one radially extending and curving slot.
6. The intervertebral spacer device of claim 3, wherein the at least one
slot passes partially through the circumferential extent.
- 30 7. The intervertebral spacer device of claim 3, wherein the at least one
slot comprises a single radial slot passing completely through the circumferential
extent.

8. The intervertebral spacer device of claim 1, wherein the at least one wave washer comprises at least one ring-shaped wave washer.

5 9. The intervertebral spacer device of claim 8, wherein the at least one ring-shaped wave washer has a circumferential extent having at least one radially extending slot.

10 10. The intervertebral spacer device of claim 9, wherein the circumferential extent has a single radially extending slot that passes completely through the circumferential extent.

15 11. The intervertebral spacer device of claim 9, wherein the at least one radially extending slot comprises at least one radially extending slot that passes partially through the circumferential extent.

12. The intervertebral spacer device of claim 8, wherein the at least one wave washer comprises a plurality of ring-shaped wave washers.

20 13. The intervertebral spacer device of claim 12, wherein the plurality of ring-shaped wave washers comprises a plurality of ring-shaped wave washers concentrically disposed relative to one another.

25 14. The intervertebral spacer device of claim 13, wherein the plurality of concentrically disposed ring-shaped wave washers has a radially diminishing amplitude.

30 15. The intervertebral spacer device of claim 1, wherein the at least one wave washer comprises at least one spiral-shaped wave washer.

16. The intervertebral spacer device of claim 15, wherein the spiral-shaped wave washer has a radially diminishing amplitude.

17. The intervertebral spacer device of claim 1, wherein at least one of said

first and second plates comprises a wave washer securing element mounted to the inner surface thereof.

18. The intervertebral spacer device of claim 17, wherein the wave washer
5 securing element comprises a fastener.

19. The intervertebral spacer device of claim 17, wherein the wave washer
securing element comprises a flanged fastener.

10 20. The intervertebral spacer device of claim 19, wherein the wave washer
securing element comprises a post having at least one laterally extending spoke.

21. The intervertebral spacer device of claim 20, wherein the post is
rotatable relative to the at least one of said first and second plates to which the post is
15 mounted.

22. The intervertebral spacer device of claim 20, wherein the at least one
laterally extending spoke comprises a plurality of laterally extending spokes, and the
at least one wave washer is secured to the at least one of said first and second plates
20 with a circumferential extent of the at least one wave washer being maintained,
between the spokes and the at least one of said first and second plates.

23. The intervertebral spacer device of claim 22, wherein each spoke
extends parallel to a wave of the at least one wave washer.
25

24. The intervertebral spacer device of claim 19, wherein the flanged
fastener has a post portion and a flanged portion, and wherein the post portion has a
diameter smaller than a diameter of a central bore of the at least one wave washer,
and a length greater than a thickness of a portion of a circumferential extent of the at
30 least one wave washer surrounding the central bore, and wherein the flanged portion
has a diameter greater than a diameter of the central bore, and wherein the at least
one wave washer is secured to the at least one of said first and second plates with the
circumferential extent portion surrounding the central bore being maintained,
between the flanged portion and the at least one of said first and second plates, such

that the at least one wave washer is free to rotate relative to the at least one of said first and second plates.

25. The intervertebral spacer device of claim 1, wherein at least one of said first and second plates comprises a circular recess within which an end of the at least one wave washer is disposed.

26. The intervertebral spacer device of claim 25, further comprising a retaining element fastened to the at least one of said first and second plates having the circular recess, the retaining element preventing the dislocation of the end of the at least one wave washer from the circular recess.

27. The intervertebral spacer device of claim 26, wherein the retaining element comprises a shield.

28. The intervertebral spacer device of claim 1, wherein the at least one wave washer has a central bore forming a curvate socket and at least one of said first and second plates has on its inner surface a semispherical protuberance that is couplable to the curvate socket.

29. The intervertebral spacer device of claim 28, wherein the semispherical protuberance comprises at least one radial slot such that the semispherical protuberance is radially deflectable upon the application of a radially inwardly directed force.

30. The intervertebral spacer device of claim 29, wherein the semispherical protuberance further comprises an axial bore into which a deflection preventing element is disposable to prevent the radial deflection of the semispherical protuberance.

31. The intervertebral spacer device of claim 30, wherein the deflection preventing element comprises a rivet.

32. The intervertebral spacer device of claim 28, wherein the semispherical

protuberance is rotatably and angulatably coupleable to the curvate socket.

33. The intervertebral spacer device of claim 32, wherein the semispherical protrusion comprises a radially deflectable semispherical portion and the curvate socket has an interior volume and an opening leading to the interior volume, the curvate socket accommodating the semispherical portion for free rotation and angulation therein, the semispherical portion fitting through the opening only when radially deflected, the semispherical portion being adapted to receive a deflection preventing element that when applied to the semispherical portion prevents the semispherical portion from fitting through the opening.

34. The intervertebral spacer device of claim 1, wherein the at least one wave washer has a circumferential extent having a thickness that is radially varying.

35. The intervertebral spacer device of claim 34, wherein the circumferential extent is thicker at an inner portion of the extent as compared with an outer portion of the extent.

36. The intervertebral spacer device of claim 34, wherein the circumferential extent is thinner at an inner portion of the extent as compared with an outer portion of the extent.

37. The intervertebral spacer device of claim 1, wherein the at least one wave washer has a circumferential extent that is radially wavy.

38. The intervertebral spacer device of claim 1, wherein the at least one wave washer has a circumferential extent that has at least one concentric groove.

39. The intervertebral spacer device of claim 38, wherein the at least one concentric groove includes a plurality of radially spaced concentric grooves, at least one of the plurality of radially spaced concentric grooves having a length.

40. The intervertebral spacer device of claim 39, wherein the at least one of the plurality of radially spaced concentric grooves has a depth and a width, and at

least one of the width and the depth is uniform along the length.

41. The intervertebral spacer device of claim 39, wherein the at least one of the plurality of radially spaced concentric grooves has a depth and a width, and at least one of the width and the depth varies along the length.

42. The intervertebral spacer device of claim 39, wherein each of the plurality of radially spaced concentric grooves has a respective length, a respective depth along the respective length, and a respective width along the respective length, and wherein at least one of the depths is different than at least one other of the depths, and wherein at least one of the widths is different than at least one other of the widths.

43. The intervertebral spacer device of claim 42, wherein each of the plurality of radially spaced concentric grooves is at a respective distance from an outer edge of the circumferential extent, wherein the depths increase incrementally with decreasing said distances, and the widths increase incrementally with decreasing said distances.

44. The intervertebral spacer device of claim 42, wherein each of the plurality of radially spaced concentric grooves is at a respective distance from an outer edge of the circumferential extent, wherein the depths decrease incrementally with decreasing said distances, and the widths decrease incrementally with decreasing said distances.

45. The intervertebral spacer device of claim 1, wherein the at least one wave washer has a circumferential extent having at least one radially extending wave valley having a depth and a width, wherein at least one of the depth and the width of the valley radially varies.

46. The intervertebral spacer device of claim 45, wherein the depth and the width increase incrementally with increasing radial distance from a central bore of the at least one wave washer.

47. The intervertebral spacer device of claim 1, wherein the at least one wave washer comprises at least one conical-shaped wave washer.

5 48. The intervertebral spacer device of claim 47, wherein the at least one conical-shaped wave washer has a circumferential extent having at least one radially extending slot.

10 49. The intervertebral spacer device of claim 47, wherein the at least one conical-shaped wave washer has a circumferential extent having at least one radially extending and curving slot.

15 50. The intervertebral spacer device of claim 47, wherein the at least one conical-shaped wave washer has a central bore forming a curvate socket and at least one of said first and second plates has on its inner surface a semispherical protuberance that is rotatably and angulatably couplable to the curvate socket.

51. The intervertebral spacer device of claim 1, wherein the at least one wave washer is comprises at least one semispherical-shaped wave washer.

20 52. The intervertebral spacer device of claim 51, wherein the at least one semispherical-shaped wave washer has a circumferential extent having at least one radially extending slot.

25 53. The intervertebral spacer device of claim 51, wherein the at least one semispherical-shaped wave washer has a circumferential extent having at least one radially extending and curving slot.

30 54. The intervertebral spacer device of claim 51, wherein the at least one semispherical-shaped wave washer has a central bore forming a curvate socket and at least one of said first and second plates has on its inner surface a semispherical protuberance that is rotatably and angulatably couplable to the curvate socket.

55. The intervertebral spacer device of claim 1, wherein the at least one wave washer comprises a central bore from which an upwardly extending circumferential extent portion extends, and from which central bore a downwardly extending circumferential extent portion extends.

5

56. The intervertebral spacer device of claim 55, wherein at least one of the portions is conical-shaped.

57. The intervertebral spacer device of claim 55, wherein at least one of the portions is semispherical shaped.

10

58. The intervertebral spacer device of claim 1, wherein at least one of said first and second plates comprises on its outer surface an element that is deformably reshapeable under anatomical loads to securably engage a vertebral body endplate.

15

59. The intervertebral spacer device of claim 58, wherein said convex element comprises a mesh.

60. The intervertebral spacer device of claim 59, wherein the mesh has a resting shape in the shape of a dome convexly extending from the at least one of said first and second plates.

20

61. The intervertebral spacer device of claim 59, wherein the mesh is laser-welded to the at least one of said first and second plates.

25

62. The intervertebral spacer device of claim 59, wherein the mesh comprises titanium.

63. The intervertebral spacer device of claim 59, further comprising an osteoconductive feature adjacent the mesh.

30

64. The intervertebral spacer device of claim 63, wherein the osteoconductive feature adjacent the mesh comprises a porous area on the at least one of said first and second plates.

65. An artificial intervertebral disc, comprising:

first and second plates disposed to provide opposed respective inwardly facing support surfaces of said plates, and to provide respective outwardly facing surfaces of said plates; and

at least one wave washer disposed between the inwardly facing support surfaces such that a compressive load applied to the outwardly facing surfaces is resisted by said at least one wave washer; wherein

said at least one wave washer includes a central bore forming a curvate socket; and wherein

at least one of said first and second plates includes on its inwardly facing support surface a semispherical protuberance that is rotatably and angulatably couplable to the curvate socket such that the plates are rotatable and angulatable relative to one another thereby.

66. The artificial intervertebral disc of claim 65, wherein the semispherical protrusion comprises a radially deflectable semispherical portion and the curvate socket has an interior volume and an opening leading to the interior volume, the curvate socket accommodating the semispherical portion for free rotation and angulation therein, the semispherical portion fitting through the opening only when radially deflected, the semispherical portion being adapted to receive a deflection preventing element that when applied to the semispherical portion prevents the semispherical portion from fitting through the opening.

67. The artificial intervertebral disc of claim 66, wherein the semispherical protuberance comprises at least one radial slot such that the semispherical protuberance is radially deflectable upon the application of a radially inwardly directed force.

68. The artificial intervertebral disc of claim 67, wherein the semispherical protuberance further comprises an axial bore into which the deflection preventing element is disposable to prevent the radial deflection of the semispherical protuberance.

69. The artificial intervertebral disc of claim 68, wherein the deflection preventing element comprises a rivet.

5 70. The artificial intervertebral disc of claim 65, wherein the at least one wave washer is selected from the group consisting of a ring-shaped wave washer, a spiral-shaped wave washer, a conical-shaped wave washer, and a semispherical-shaped wave washer.

10 71. The artificial intervertebral disc of claim 70, wherein the at least one wave washer is disposed concentrically with at least one other wave washer.

72. The artificial intervertebral disc of claim 71, wherein the plurality of concentrically disposed wave washers has a radially diminishing amplitude.

15 73. The artificial intervertebral disc of claim 70, wherein the spiral-shaped wave washer has a radially diminishing amplitude.

20 74. The artificial intervertebral disc of claim 70, wherein the at least one wave washer has a circumferential extent comprising at least one radially extending slot.

75. The artificial intervertebral disc of claim 74, wherein the at least one radially extending slot comprises at least one radially extending and curving slot.

25 76. The artificial intervertebral disc of claim 65, wherein at least one of said first and second plates comprises a circular recess, on its inwardly facing support surface, within which an end of the at least one wave washer is disposed.

30 77. The artificial intervertebral disc of claim 76, further comprising a retaining element fastened to the at least one of said first and second plates having the circular recess, the retaining element preventing the dislocation of the end of the at least one wave washer from the circular recess.

78. The artificial intervertebral disc of claim 77, wherein the retaining element comprises a shield.

5 79. The artificial intervertebral disc of claim 65, wherein at least one of the outwardly facing surfaces comprises a vertebral body contact element that is deformably reshapable under anatomical loads to securably engage a vertebral body endplate.

10 80. An artificial intervertebral disc, comprising:
first and second plates disposed to provide opposed respective inwardly facing support surfaces of said plates, and to provide respective outwardly facing surfaces of said plates; and
at least one wave washer rotatably coupled to the inwardly facing support surface of at least one of said first and second plates by a wave washer securing
15 element such that the plates are made rotatable relative to one another thereby, and such that a compressive load applied to the outwardly facing surfaces is resisted by said at least one wave washer.

20 81. The artificial intervertebral disc of claim 80, wherein the wave washer securing element comprises a fastener.

82. The artificial intervertebral disc of claim 80, wherein the wave washer securing element comprises a flanged fastener.

25 83. The artificial intervertebral disc of claim 82, wherein the wave washer securing element comprises a post having at least one laterally extending spoke.

84. The artificial intervertebral disc of claim 83, wherein the post is rotatable relative to the at least one of said first and second plates.

30

85. The artificial intervertebral disc of claim 83, wherein the at least one laterally extending spoke comprises a plurality of laterally extending spokes, and the at least one wave washer is secured to the at least one of said first and second plates with a circumferential extent of the at least one wave washer being maintained, between the spokes and the at least one of said first and second plates.

86. The artificial intervertebral disc of claim 85, wherein each spoke extends parallel to a wave of said at least one wave washer.

87. The artificial intervertebral disc of claim 82, wherein the flanged fastener has a post portion and a flanged portion, and wherein the post portion has a diameter smaller than a diameter of a central bore of said at least one wave washer, and a length greater than a thickness of a portion of a circumferential extent of said at least one wave washer surrounding the central bore, and wherein the flanged portion has a diameter greater than a diameter of the central bore, and wherein said at least one wave washer is secured to the at least one of said first and second plates with the circumferential extent portion surrounding the central bore being maintained, between the flanged portion and the at least one of said first and second plates, such that said at least one wave washer is rotatable relative to the at least one of said first and second plates.

88. The artificial intervertebral disc of claim 80, wherein said at least one wave washer is selected from the group consisting of a ring-shaped wave washer, a spiral-shaped wave washer, a conical-shaped wave washer, a semispherical-shaped wave washer, and a plurality of wave washers..

89. The artificial intervertebral disc of claim 88, wherein the plurality of wave washers comprises a plurality of ring-shaped wave washers concentrically disposed relative to one another.

90. The artificial intervertebral disc of claim 89, wherein the plurality of concentrically disposed ring-shaped wave washers has a radially diminishing amplitude.

91. The artificial intervertebral disc of claim 88, wherein the spiral-shaped wave washer has a radially diminishing amplitude.

5 92. The artificial intervertebral disc of claim 88, wherein said at least one wave washer has a circumferential extent comprising at least one radially extending slot.

93. The artificial intervertebral disc of claim 92, wherein the at least one radially extending slot comprises at least one radially extending and curving slot.

10 94. The artificial intervertebral disc of claim 80, wherein at least one of said first and second plates comprises a circular recess, on its inwardly facing support surface, within which an end of said at least one wave washer is disposed.

15 95. The artificial intervertebral disc of claim 94, further comprising a retaining element fastened to the at least one of said first and second plates having the circular recess, the retaining element preventing the dislocation of the end of said at least one wave washer from the circular recess.

20 96. The artificial intervertebral disc of claim 95, wherein the retaining element comprises a shield.

25 97. The artificial intervertebral disc of claim 80, wherein at least one of the outwardly facing surface comprises a vertebral body contact element that is deformably reshapable under anatomical loads to securably engage a vertebral body endplate.

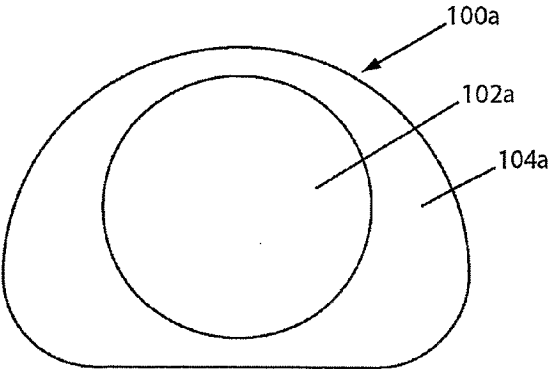


FIGURE 1.1

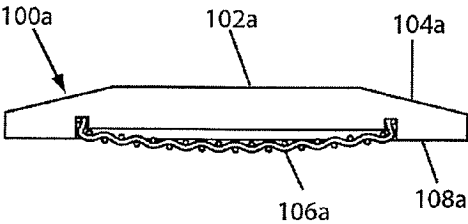


FIGURE 1.2

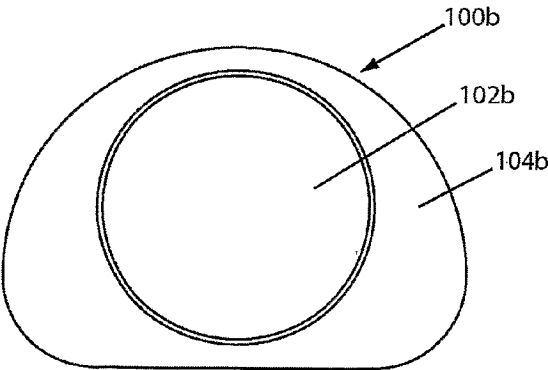


FIGURE 1.3

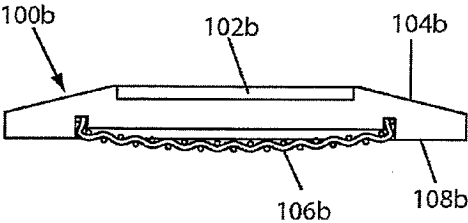


FIGURE 1.4

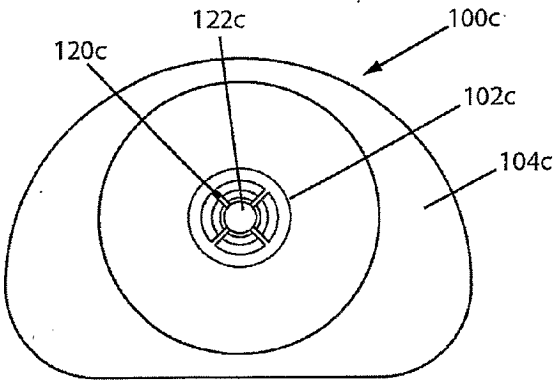


FIGURE 1.5

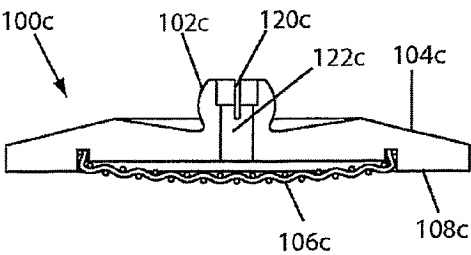


FIGURE 1.6

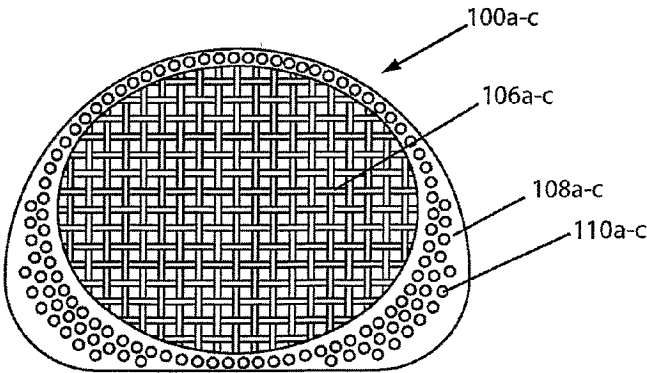


FIGURE 1.7

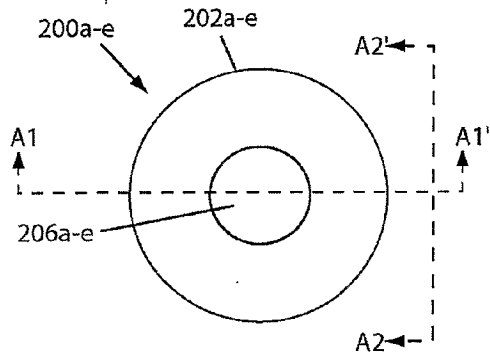


FIGURE 2.1

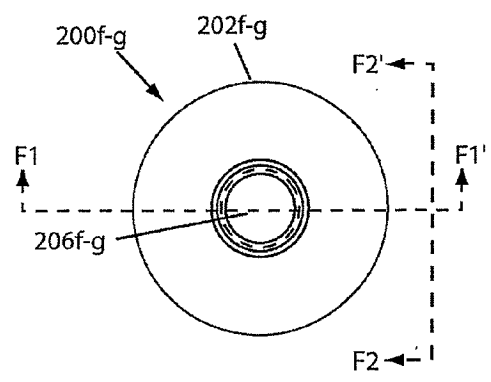


FIGURE 2.4

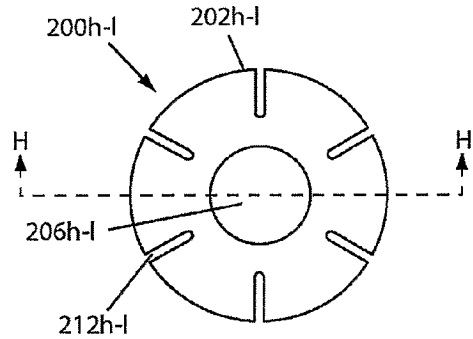


FIGURE 2.2

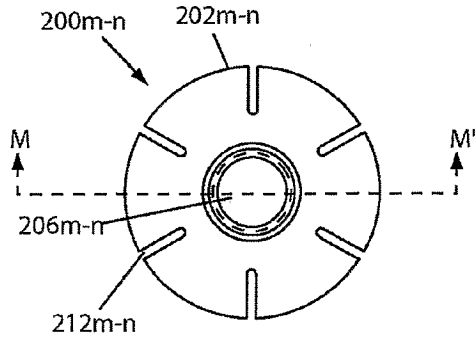


FIGURE 2.5

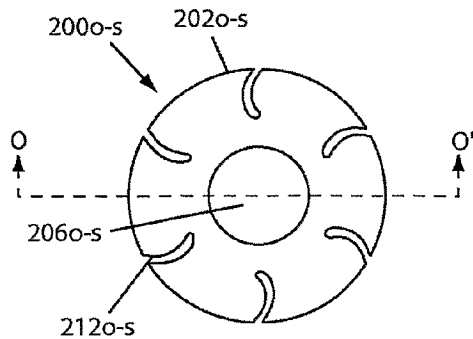


FIGURE 2.3

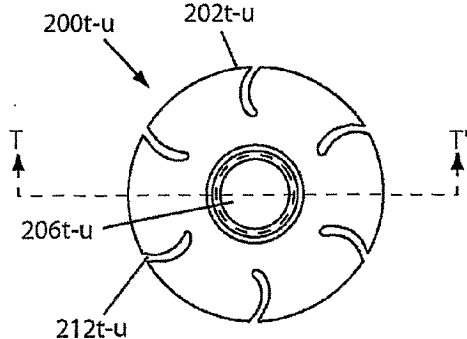


FIGURE 2.6

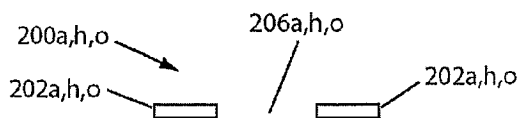


FIGURE 3.1

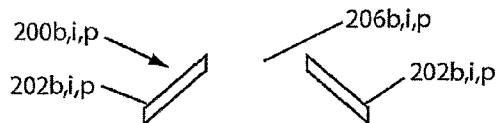


FIGURE 3.2

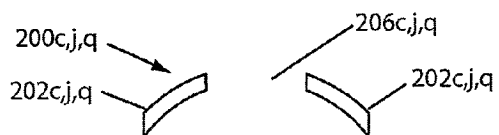


FIGURE 3.3

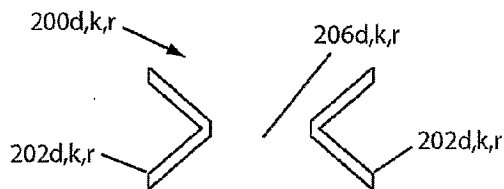


FIGURE 3.4

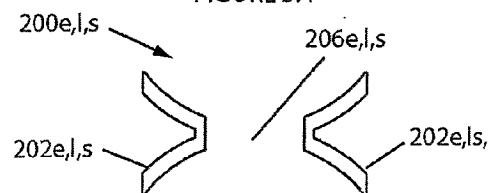


FIGURE 3.5

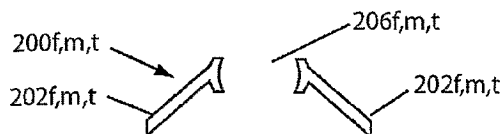


FIGURE 3.6

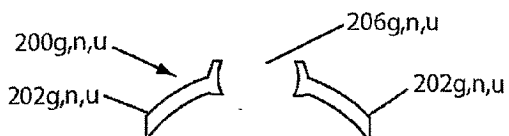


FIGURE 3.7

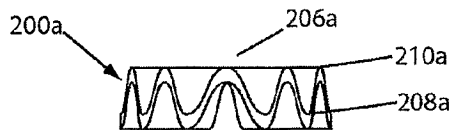


FIGURE 3.8



FIGURE 3.9



FIGURE 3.10

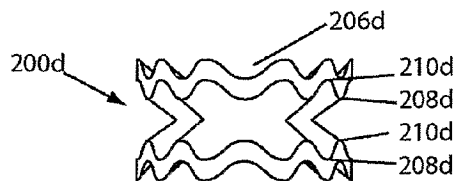


FIGURE 3.11

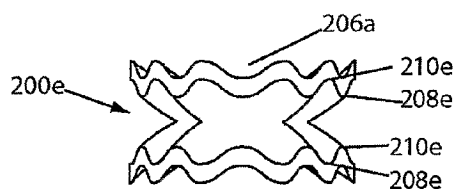


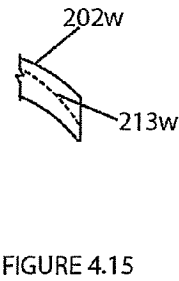
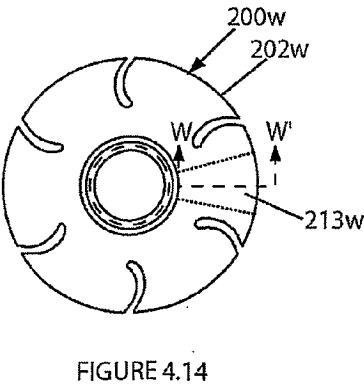
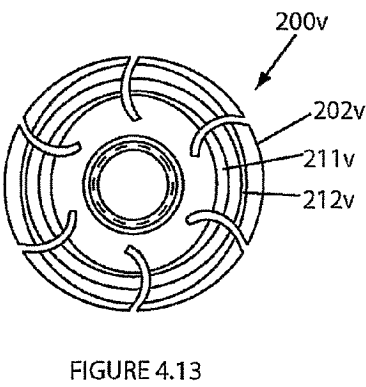
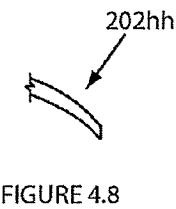
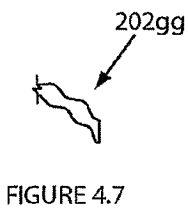
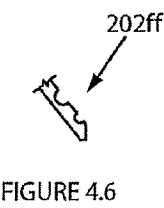
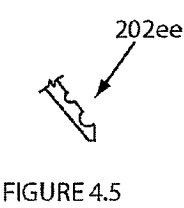
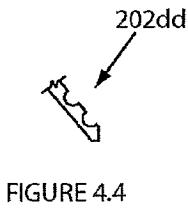
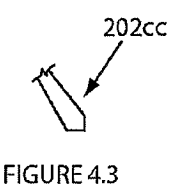
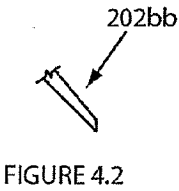
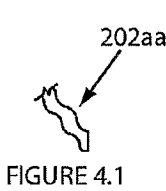
FIGURE 3.12



FIGURE 3.13



FIGURE 3.14



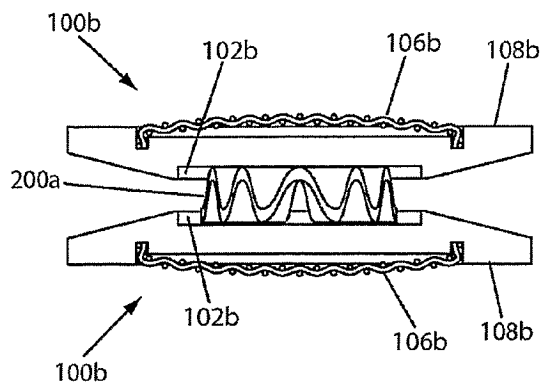


FIGURE 5.1

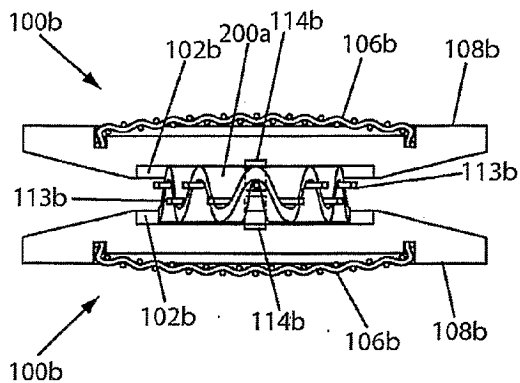


FIGURE 5.2

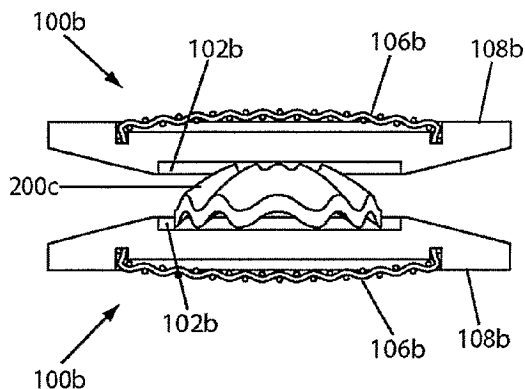


FIGURE 5.3

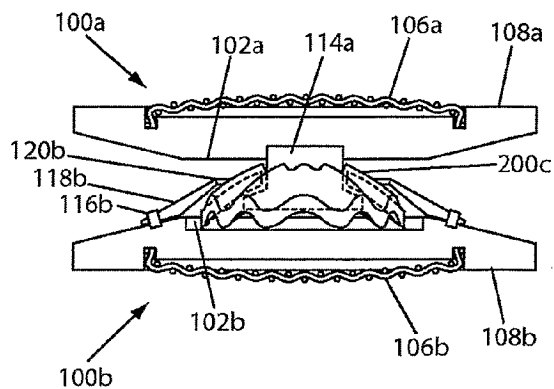


FIGURE 5.4

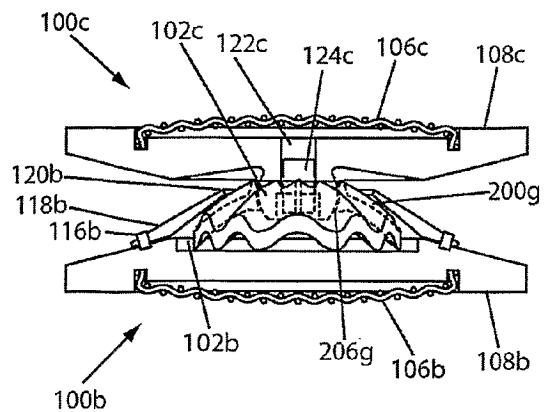


FIGURE 5.5

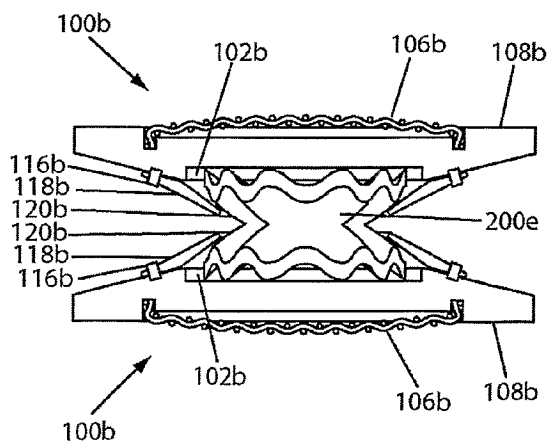


FIGURE 5.6

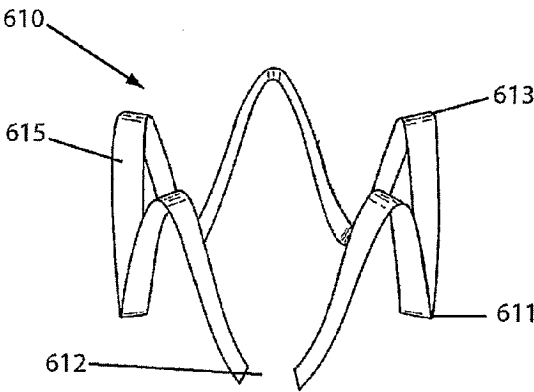


FIGURE 6.1

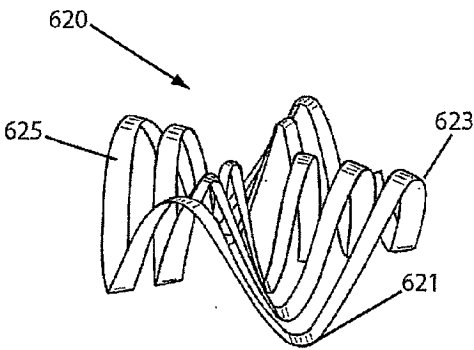


FIGURE 6.2

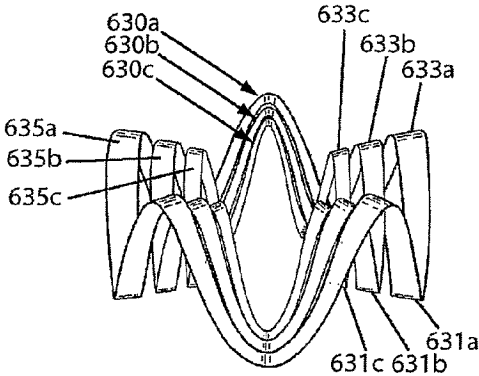


FIGURE 6.3

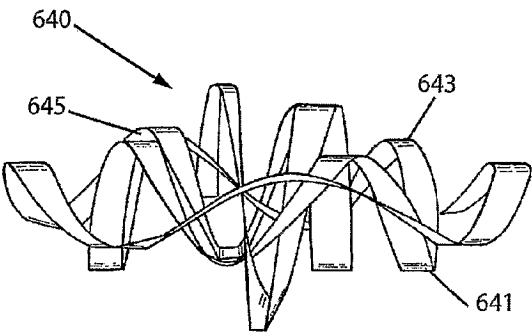


FIGURE 6.4

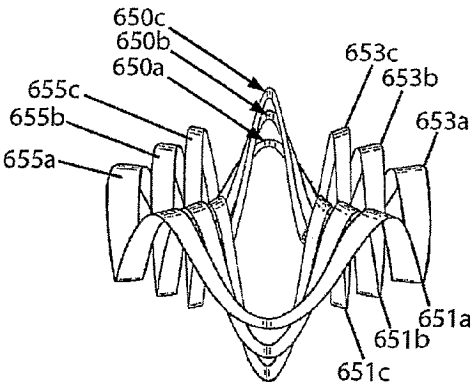


FIGURE 6.5

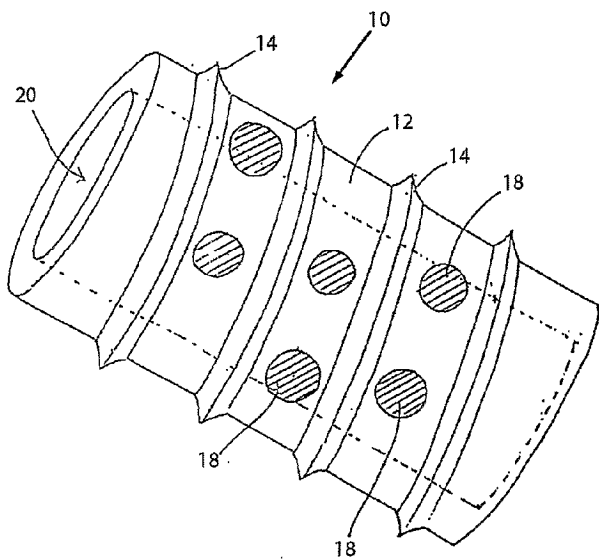


FIGURE 7
PRIOR ART

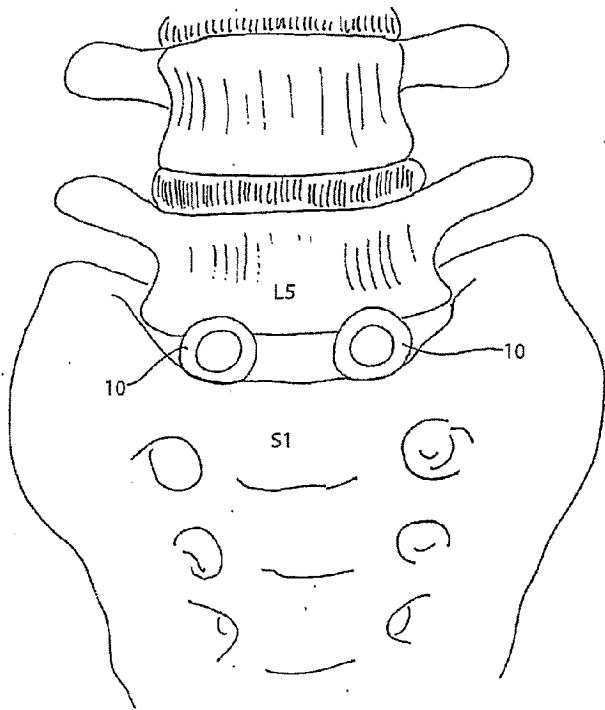


FIGURE 8
PRIOR ART

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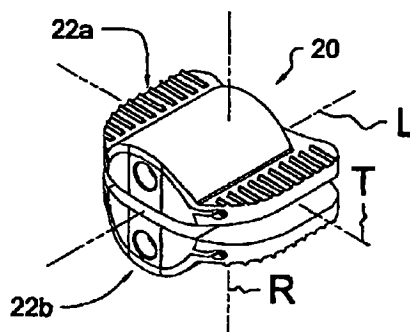
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(54) Title: ARTICULAR DISC PROSTHESIS AND METHOD FOR IMPLANTING THE SAME



(57) Abstract: An articular disc prosthesis and method of implanting the same within an intervertebral space between adjacent vertebral bodies. The prosthesis includes a pair of articular components and an articular ball disposed therebetween. Each of the articular components includes an outer shell portion and a removable inner insert portion. The insert portion includes a concave articular surface sized and shaped to receive a portion of the articular ball to provide articulating motion between the articular components. The outer shell portion includes a central hemi-cylindrical portion, a pair of laterally extending flanges, and an axially extending lip. Following removal of the natural intervertebral disc, a pair of hemi-cylindrical recesses is formed along a central region of the adjacent vertebral bodies to a predetermined depth. The prosthesis is implanted within the prepared disc space by axially displacing the hemi-cylindrical central portions of the articular components along the hemi-cylindrical recesses in the vertebral bodies. The lateral flanges and the axial lip of the articular components bear against the endplates of the adjacent vertebral bodies to stabilize the prosthesis and to prevent subsidence.

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Disc 05002 ✓
05001
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ARTICULAR DISC PROSTHESIS AND METHOD FOR IMPLANTING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

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The present application claims the benefit of Provisional Application Serial No. 60/375,354 filed on April 25, 2002, the contents of which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

10

The present invention relates generally to the field of spinal implants, and more particularly relates to an articular disc prosthesis and method of implantation for use in the total or partial replacement of a natural intervertebral disc.

BACKGROUND OF THE INVENTION

15

In the treatment of diseases, injuries or malformations affecting spinal motion segments, and especially those affecting disc tissue, it has long been known to remove some or all of a degenerated, ruptured or otherwise failing disc. In cases involving intervertebral disc tissue that has been removed or is otherwise absent from a spinal motion segment, corrective measures are indicated to insure the proper spacing of the vertebrae formerly separated by the removed disc tissue.

20

In some instances, the two adjacent vertebrae are fused together using transplanted bone tissue, an artificial fusion component, or other compositions or devices. Spinal fusion procedures, however, have raised concerns in the medical community that the bio-mechanical rigidity of intervertebral fusion may predispose neighboring spinal motion segments to rapid deterioration. More specifically, unlike a natural intervertebral disc, spinal fusion prevents the fused vertebrae from pivoting and rotating with respect to one another. Such lack of mobility tends to increase stresses on adjacent spinal motion segments. Additionally, several conditions may develop within adjacent spinal motion segments, including disc degeneration, disc herniation, instability, spinal stenosis, spondylosis and facet joint arthritis. Consequently, many patients may require additional disc removal and/or another type of surgical procedure as a result of spinal fusion. Alternatives to spinal fusion are therefore desirable.

25

Several different types of intervertebral disc arthroplasty devices have been proposed for preventing the collapse of the intervertebral space between adjacent vertebrae while maintaining a certain degree of stability and range of pivotal and rotational motion

30

therebetween. Such devices typically include two or more articular components that are attached to respective upper and lower vertebrae. The articular components are anchored to the upper and lower vertebrae by a number of methods, including the use of bone screws that pass through corresponding openings in each of the elements and thread into vertebral bone, and/or by the inclusion of spikes or teeth that penetrate the vertebral endplates to inhibit migration or expulsion of the device. The articular components are typically configured to allow the elements, and correspondingly the adjacent vertebrae, to pivot and/or rotate relative to one another.

As discussed above, prior intervertebral disc arthroplasty devices are relatively difficult to implant between adjacent vertebrae. To implant such devices, the adjacent vertebrae are spread apart a distance that is somewhat greater than the normal distance separating the vertebrae so that the device can be maneuvered between the vertebrae and the anchors can be engaged to the vertebral endplates. Such an operation presents a risk of injury to the vertebrae caused by misplacement and/or scratching of the vertebral endplates or other tissue by the anchors. Such operation also presents a risk of injury resulting from over-distraction of the intervertebral space. As also discussed above, other types of prior arthroplasty devices require the threading of bone screws or another type of fastener into the adjacent vertebrae. However, this type of anchoring method requires precise placement and orientation of the bone screws to provide adequate anchoring and to avoid injury to adjacent tissue or vertebral structures. Moreover, prior methods of implanting arthroplasty devices do not reliably position the device at the proper location within the intervertebral disc space.

The articular components associated with prior arthroplasty devices are also prone to wear, particularly in cases where the abutting surface area of the articular joint is relatively small. Generally, as the abutting surface area of an articular joint is reduced, contact stress is correspondingly increased which may reduce the overall life of the joint. As a result, worn out components must be periodically replaced to avoid malfunctioning or potential breakage of the arthroplasty device.

Thus, there is a general need in the industry to provide an improved articular disc prosthesis and a method of implanting the same than is currently available within the industry. The present invention meets this need and provides other benefits and advantages in a novel and unobvious manner.

SUMMARY OF THE INVENTION

The present invention relates generally to an articular disc prosthesis and a method of implanting the same. While the actual nature of the invention covered herein can only
5 be determined with reference to the claims appended hereto, certain forms of the invention that are characteristic of the preferred embodiments disclosed herein are described briefly as follows.

One form of the present invention is directed to an articular disc prosthesis, including a first articular component having a first bearing surface adapted to engage a
10 first vertebra, and a second articular component having second bearing surface adapted to engage a second vertebra, with the first and second bearing surfaces defining a space therebetween. At least one of the first and second articular components includes a concave articular surface that cooperates with a corresponding convex articular surface to provide articulating motion between the first and second articular components, with
15 at least a portion of the concave articular surface extending beyond the space between the first and second bearing surfaces.

Another form of the present invention is directed to an articular disc prosthesis for replacement of a natural intervertebral disc, including a first articular component defining a first concave articular surface, a second articular component defining a
20 second concave articular surface, and an articular ball positioned between the first and second concave articular surfaces to provide articulating motion between the first and second articular components, and wherein the articular ball has a diameter greater than a height of the natural intervertebral disc.

25 Another form of the present invention is directed to an articular disc prosthesis, including a first articular component adapted to engage a first vertebra, a second articular component adapted to engage a second vertebra, and wherein each of the first and second articular components extends along an axis and includes a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally
30 from the central axial portion in generally opposite directions.

Another form of the present invention is directed to an articular disc prosthesis, including first and second modular articular components, with each of the modular

articular components having an outer shell portion configured to engage a corresponding one of first and second vertebrae, and an inner insert portion removably engaged with the outer shell portion. The inner insert portion includes an articular surface cooperating with a corresponding articular surface to provide articulating
5 motion between the first and second modular articular components.

Another form of the present invention is directed to a method of implanting an articular disc prosthesis between first and second vertebrae, including providing an articular disc prosthesis having a first articular component adapted to engage a first vertebra and a second articular component adapted to engage a second vertebra, with
10 each of the first and second articular components extending along an axis and including a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally from the central axial portion in generally opposite directions. The method further includes removing at least a portion of a natural intervertebral disc from between the first and second vertebrae to form an intervertebral space, forming an
15 elongate recess along a central region of each of the first and second vertebrae, and implanting the articular disc prosthesis within the intervertebral space by inserting the central axial portions of the first and second articular components within the elongate recesses formed along the first and second vertebrae.

It is one object of the present invention to provide an improved articular disc
20 prosthesis. It is another object of the present invention to provide an improved method of implanting an articular disc prosthesis within the intervertebral disc space between adjacent vertebral bodies.

Further objects, features, advantages, benefits, and aspects of the present invention will become apparent from the drawings and description contained herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an articular disc prosthesis according to one form of the present invention.

5 FIG. 2 is a front elevational view of the articular disc prosthesis illustrated in FIG. 1.

FIG. 3 is a side elevational view of the articular disc prosthesis illustrated in FIG. 1.

10 FIG. 4 is an exploded perspective view of the articular disc prosthesis illustrated in FIG. 1.

FIG. 5 is a top view of an endplate according to one embodiment of the present invention for use with the articular disc prosthesis illustrated in FIG. 1.

FIG. 6 is an end view of the endplate illustrated in FIG. 5.

FIG. 7 is a side view of the endplate illustrated in FIG. 5.

15 FIG. 8 is a sectional view of the endplate illustrated in FIG. 5, taken along line 8-8 of FIG. 5.

FIG. 9 is an end view of an insert according to one embodiment of the present invention for use with the articular disc prosthesis illustrated in FIG. 1.

FIG. 10 is a top view of the insert illustrated in FIG. 9.

20 FIG. 11 is a side view of the insert illustrated in FIG. 10.

FIG. 12 is a sectional view of the insert illustrated in FIG. 9, taken along line 12-12 of FIG. 9.

FIG. 13 is a lateral view of a portion of the spinal column, illustrating a pair of adjacent upper and lower vertebrae separated by a natural intervertebral disc.

25 FIG. 14 is an anterior view of the portion of the spinal column shown in FIG. 13, illustrating the removal of portions of the upper and lower vertebrae to accommodate insertion of the articular disc prosthesis illustrated in FIG. 1 therebetween.

FIG. 15 is a lateral view of the portion of the spinal column shown in FIG. 14.

30 FIG. 16 is an anterior view of the portion of the spinal column shown in FIG. 14, illustrating implantation of the articular disc prosthesis between the upper and lower vertebrae.

FIG. 17 is a partial sectional view of the portion of the spinal column shown in FIG. 16, illustrating implantation of the articular disc prosthesis between the upper and lower vertebrae.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no
5 limitation of the scope of the invention is hereby intended, and that any alterations and further modifications in the illustrated devices, and any further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIGS. 1-4, shown therein is an articular disc prosthesis 20
10 according to one form of the present invention. The disc prosthesis 20 extends generally along a longitudinal axis L and includes an upper articular component 22a, a lower articular component 22b, and an articular ball 24 disposed between the upper and lower articular components 22a, 22b. The articular ball 24 defines a convex articular surface 25 and preferably has a spherical configuration. However, it should be
15 understood that the articular ball 24 may take on other configurations as well, such as, for example, an elliptical or eccentric configuration.

The articular components 22a, 22b are configured substantially identical to one another. Therefore, the description and/or illustration of one of the articular components 22a, 22b applies equally to the other. In a preferred embodiment of the
20 invention, the articular components 22a, 22b have a modular configuration. More specifically, each of the articular components 22a, 22b preferably includes an outer shell or endplate 26 and an inner articular cup or insert 28. As will be discussed in further detail below, the articular insert 28 can be removed from the endplate 26 and replaced with an insert of the same type or of a different type. The articular insert 28 is
25 secured in position relative to the endplate 26 by a first set of fasteners 30. A second set of fasteners 32 is preferably included to engage the first set of fasteners to prevent the first set of fasteners 30 from loosening and backing out. In one embodiment of the invention, the fasteners 30, 32 are threaded set screws. However, it should be
30 understood that other types and configurations of fasteners are also contemplated as would occur to one of ordinary skill in the art.

The upper and lower articular components 22a, 22b and the articular ball 24 cooperate to form an articulating joint that is sized and configured for disposition

within an intervertebral disc space between adjacent vertebral bodies. Specifically, the convex outer surface 25 of the articular ball 24 cooperates with corresponding concave surfaces formed in the articular inserts 28 to provide relative articulating motion between the articular components 22a, 22b. In a preferred embodiment of the invention, such articulating motion includes both pivotal and rotational movement to maintain or restore motion substantially similar to normal bio-mechanical motion provided by a natural intervertebral disc.

In one embodiment of the invention, the articular components 22a, 22b are permitted to rotate relative to one another about a rotational axis R. In another embodiment of the invention, the articular components 22a, 22b are permitted to pivot relative to one another about a number of axes, including lateral or side-to-side pivotal movement about the longitudinal axis L and anterior-posterior pivotal movement about a transverse axis T. In a further embodiment of the invention, the articular components 22a, 22b are permitted to pivot relative to one another about any axis which lies in a plane that intersects the longitudinal axis L and the transverse axis T. Although the disc prosthesis 20 has been illustrated and described as providing a combination of various articulating movements, it should be understood that other variations and combinations of articulating movements are also contemplated as falling within the scope of the present invention. It should also be understood that other types of articulating movement are also contemplated, such as, for example, relative translational or linear movement.

Although the various components of the articular disc prosthesis 20 may be formed from a wide variety of materials, following is a listing of various component materials according to one embodiment of the present invention. It should be understood, however, that the components of the disc prosthesis 20 may be formed of materials other than those specifically listed below, including any bio-compatible material that would be known to one of ordinary skill in the art or any other equivalent material.

The outer endplates 26 are preferably formed of a polymeric material, such as, for example, a polyaryletherketone polymer or polyethylene. In other embodiments of the invention, the outer endplates 26 may be formed of titanium, stainless steel, other types of metallic materials, or a ceramic material. The outer surfaces of the endplate 26

that are intended to be in direct contact with vertebral bone are preferably coated with a bone-growth promoting substance, such as, for example, a hydroxyapatite (HA) coating formed of calcium phosphate. The articular inserts 28 are preferably formed of a metallic material, such as, for example, cobalt-chrome-molybdenum metallic alloy (ASTM F-799 or F-75). In other embodiments of the invention, the articular inserts 28 may be formed of other types of metallic materials, such as, for example, titanium or stainless steel, a ceramic material, or a polymeric material. The articular ball 24 is preferably formed of a polymeric material, such as, for example, an ultra-high molecular weight polyethylene (UHMWPE). In another embodiment of the invention, the articular ball 24 may be cross-linked by radiation, by chemical means or by any other method known to those of skill in the art. In other embodiments of the invention, the articular ball 24 may be formed of titanium, stainless steel, other types of metallic materials, or a ceramic material. In one embodiment of the invention, the first set of fasteners 30 is formed of a polymeric material, such as, for example, a polyaryletherketone polymer. Preferably, the first set of fasteners 30 is formed of the same material as the endplates 26. In another embodiment of the invention, the second set of fasteners 32 is formed of a metallic material, such as, for example, cobalt-chrome-molybdenum metallic alloy. Preferably, the second set of fasteners 32 is formed of the same material as the articular inserts 28. In other embodiments of the invention, the first and second sets of fasteners 30, 32 may be formed of other types of materials, such as, for example, titanium, stainless steel, other types of metallic materials, a ceramic material, or a polymeric material.

Referring to FIGS. 5-8, shown therein are various details regarding the configuration of the outer endplates 26. In one embodiment of the invention, the endplates 26 are each comprised of a central axial portion 50 and a lip portion 52 extending about a periphery of the axial portion 50. The peripheral lip portion 52 is comprised of a pair of flanges or wings 54, 56 extending laterally from the central portion 50, and a flange or lip 58 extending axially from the central portion 50. As shown in FIG. 5, the outer peripheral profile of the endplate 50 is preferably sized and shaped to substantially correspond to the size and shape of the vertebral endplate of an adjacent vertebra.

In one embodiment of the invention, the central axial portion 50 has a hemi-

cylindrical configuration, including an outer surface 60 defining a convex lateral curvature extending along an axial length l . It should be understood, however, that the central axial portion 50 may take on other configurations, including other types of arcuate configurations, a rectangular configuration, or various types of polygonal configurations. It should also be understood that the convex outer surface 60 may take on other shapes, including an hemi-elliptical shape or other types of arcuate and/or polygonal configurations. The axial portion 50 includes an open axial end 62, a closed axial end 64, and a concave inner surface 66. The concave inner surface 66 defines a cavity 68 extending axially between the open and closed ends 62, 64. As will be discussed below, the cavity 68 is sized and shaped to receive a corresponding portion of the articular insert 28 therein. In one embodiment of the invention, the cavity 68 has a hemi-cylindrical configuration. However, it should be understood that the cavity 68 may take on other configurations as well, including other types of arcuate configurations, a rectangular configuration, or other types of polygonal configurations.

The lateral flanges 54, 56 each include an outwardly facing bearing surface 70 and an inwardly facing surface 72. In one embodiment of the invention, the outwardly facing bearing surface 70 is contiguous with the hemi-cylindrical outer surface 60 of the central axial portion 50. Similarly, the inwardly facing surface 72 is contiguous with the hemi-cylindrical inner surface 66 of the central axial portion 50. It should be understood, however, that other positions and orientations of the lateral flanges 54, 56 relative to the central axial portion 50 are also contemplated as falling within the scope of the present invention.

The outwardly facing bearing surface 70 preferably defines a number of anchor elements configured to engage vertebral bone. In one embodiment of the invention, the outwardly facing bearing surface 70 defines a number of projections or teeth 74. The teeth 74 are preferably triangular-shaped, defining pointed tips configured to bite into and securely grip vertebral bone. However, it should be understood that other configurations of the teeth 74 are also contemplated as would occur to one of skill in the art. It should also be understood that other types and configurations of anchor elements are also contemplated, such as, for example, spikes, protrusions, or various types of surface roughening features to aid in gripping vertebral bone to inhibit migration or expulsion of the disc prosthesis 20. In the illustrated embodiment of the

invention, the teeth 74 extend laterally across a substantial portion of the width of flanges 54, 56 and are positioned intermittently along the length of the flange 54, 56. However, in another embodiment of the invention, the teeth 74 may extend along the length of the flange 54, 56 and may be positioned intermittently along the width of the flange 54, 56. It should also be understood that other positions and orientations of the teeth 74 are also contemplated as falling within the scope of the present invention.

In one embodiment of the invention, each of the lateral flanges 54, 56 has a first end 80, a second end 82, and an axial passage 84 extending from the first end 80 toward the second end 82. The axial passage 84 is disposed in communication with the hollow cavity 68 defined by the central axial portion 50, the purpose of which will be discussed below. In one embodiment, the axial passage 84 includes a circular portion 86 and a slot portion 88, with the slot portion 88 extending between the hollow cavity 68 and the circular portion 86. Internal threads 87 are preferably defined along a length of the circular portion 86 of axial passage 84 which are configured to threadingly receive the first and second sets of fasteners 30, 32.

The axial lip 58 includes an outwardly facing surface 90 and an inwardly facing surface 92. In one embodiment of the invention, the outwardly facing surface 92 is substantially flat. However, it should be understood the outwardly facing surface 92 could alternatively define a number of anchor elements configured to engage vertebral bone. The axial lip 58 includes an axially facing end surface 94 extending between the lateral flanges 54, 56. In one embodiment, the axially facing end surface 94 defines a recessed area 96 extending inwardly toward the central portion 50, the purpose of which will become apparent below. The recessed area 96 preferably has an arcuate configuration; however, other configurations are also contemplated as would occur to one of skill in the art.

As illustrated in FIGS. 6 and 8, in one embodiment of the invention, the inwardly facing surfaces 72 of the lateral flanges 54, 56 preferably define an outward taper arranged at a taper angle α . The outward taper preferably extends in a lateral direction along the entire length of the flanges 54, 56 (as shown in FIG. 6).

Additionally, at least the end portions of the inwardly facing surface 72 adjacent the ends 80, 82 are preferably tapered in an axial direction at a taper angle α . (as shown in FIG. 8). The inwardly facing surface 92 of the axial lip 58 also preferably defines an

outward taper extending in an axial direction at a taper angle α . As should be appreciated, the inwardly facing surfaces 72, 92 of the lateral flanges 54, 56 and the axial lip 58 cooperate to define a substantially conically-shaped surface surrounding the central axial portion 50 and extending outwardly relative to the rotational axis R at the taper angle α . In this manner, relative pivotal movement between the articular components 22a, 22b is limited to a predetermined range of motion via abutment of the inwardly facing surfaces 72, 92 of one of the endplate 26 against the inwardly facing surfaces 72, 92 of the opposing endplate 26.

In one embodiment of the invention, the taper angle α falls within a range of between about 5 degrees and about 15 degrees, thereby limiting relative pivotal motion between the articular components 22a, 22b within a range of just over 10 degrees to just over 30 degrees. In a more specific embodiment, the taper angle α is about 7.5 degrees, thereby limiting relative pivotal motion between the articular components 22a, 22b to just over 15 degrees. It should be understood, however, that the taper angle α may take on other values to satisfy the specific articular requirements of the disc prosthesis 20, including taper angles α less than 5 degrees and greater than 15 degrees. It should also be understood that the taper angle α need not necessarily be uniform, but may instead be varied to limit relative pivotal motion between the articular components 22a, 22b within different ranges depending upon the particular pivotal axis about which the articular components 22a, 22b are being pivoted. In the illustrated embodiment of the invention, each of the endplates 26 of the articular components 22a, 22b define outwardly tapering surfaces 72, 92. However, it should be understood that in another embodiment of the invention, only one of the endplates 26 defines outwardly tapering surfaces 72, 92, with the other endplate 26 defining substantially flat inwardly facing surfaces 72, 92. In a further embodiment of the invention, both of the endplates 26 define substantially flat inwardly facing surfaces 72, 92.

Referring to FIGS. 9-12, shown therein are various details regarding the configuration of the inner articular inserts 28. In one embodiment of the invention, the articular inserts 28 are each comprised of a central body 100 and a pair of splines 102, 104 extending laterally from the central body 100. The central body 100 preferably has a shape and configuration that corresponds to the shape and configuration of the inner cavity 68 of the endplate 26. In one embodiment, the central body 100 includes a

convex outer surface 106 that corresponds to the concave inner surface 66 of the endplate 26. The central body 100 also includes a relatively flat inner surface 108 disposed generally opposite the convex outer surface 106, and a pair of opposite axial end surfaces 110, 112. An axial opening 124 is preferably formed through the end surface 112 which is configured to receive a portion of an insertion instrument or tool therein (not shown). As illustrated in FIG. 10, the central body 100 has a hemi-cylindrical configuration that closely corresponds to the hemi-cylindrical configuration of the inner cavity 68 of the endplate 26. It should be understood, however, that the central body 100 may take on other configurations, including other types of arcuate configurations, a rectangular configuration, or various types of polygonal configurations.

The central body 100 includes a relatively large recess or socket 120 extending from the flat inner surface 108. The socket 120 defines a concave articular surface 122 that cooperates with the convex articular surface 25 of the ball 24 to provide articulating motion between the articular components 22a, 22b. More particularly, the ball 24 is at least partially disposed within the socket 120 such that the convex and concave articular surfaces 25, 122 are positioned in abutment to allow pivotal and rotational movement therebetween. In a preferred embodiment of the invention, the socket 120 is shaped and configured to closely correspond to the shape and configuration of the articular ball 24. In a one embodiment, the convex surface 25 of the ball 24 has a radius that is substantially equal to the radius of curvature of the concave surface 122 of socket 120. However, it should be understood that the radius of the articular ball 24 may be sized somewhat smaller than the radius of curvature of the socket 120. In one embodiment of the invention, the diameter of the articular ball 24 falls within a range of about 10 mm to about 30 mm. In a more specific embodiment, the diameter of the articular ball 24 is approximately 19 mm. Notably, since the area of abutment between the convex surface 25 of the articular ball 24 and the concave surface 122 of the socket 120 is relatively large, internal stresses within the disc prosthesis 20 are spread out over an increased surface area, thereby resulting in decreased wear and prolonged design life of the articular ball 24 and/or the articular inserts 28. Moreover, reducing internal stresses within the disc prosthesis 20 provides

an opportunity to form the articular ball 24 and/or the articular inserts 28 from non-metallic materials, such as, for example, a polymeric material or a ceramic material.

Although the articular ball 24 and the socket 120 are illustrated as having generally smooth, uninterrupted abutting articular surfaces 25, 122, it should be
5 understood that in other embodiments of the invention, either or both of the articular surfaces 25, 122 may define one or more surface depressions to facilitate removal of matter disposed between abutting portions of the articular surfaces. Such surface depressions may include, for example, grooves, channels, passages, openings, flattened areas, or dimples. Further details regarding the inclusion of surface depressions on
10 either or both of the articular surfaces 25, 122 are disclosed in co-pending U.S. Patent Application Serial No. 10/042,589, filed on January 9, 2002 and entitled "Intervertebral Prosthetic Joint", the contents of which are hereby expressly incorporated by reference in their entirety.

The splines 102, 104 extending from the central body 100 are shaped and
15 configured to be received within the axial passages 84 extending through the flanges 54, 56 of the endplate 26. Each of the splines 102, 104 preferably includes a first axial portion 130 and a second axial portion 132. The first axial portion 130 has a lateral width that is somewhat greater than the lateral width of the second axial portion 132 so as to form an axially facing shoulder 134, the purpose of which will be discussed
20 below. As shown in FIGS. 6 and 9, the overall axial profile of the articular insert 28 substantially corresponds to that of the cavity 68 and the axial passages 84 defined within the endplate 26.

Referring once again to FIG. 4, the articular components 22a, 22b of the disc prosthesis 20 are assembled by engaging the articular inserts 28 with the endplates 26.
25 More specifically, the articular insert 28 is axially inserted into the endplate 26, with the central body 100 and the splines 102, 104 of the insert 28 being slidably displaced along the central cavity 68 and the axial passages 84 of the endplate 26. The articular insert 28 is retained within the endplate 26 by way of the first set of set screws 30. The set screws 30 are threadingly engaged along the threaded portion 87 of the axial
30 passage 84 until tightly engaged against the axial shoulder 134 of the splines 102, 104. The second set of set screws 32 are then threadingly engaged along the threaded portion 87 of the axial passage 84 until the set screws 32 engage the first set of set screws 30.

The second set of set screws 32 serve to prevent the first set of set screws 30 from loosening and backing out. Once the articular components 22a, 22b have been assembled, the articular ball 24 is positioned within the sockets 120 defined by the articular inserts 28 to form the articulating disc prosthesis 20.

5 It should be appreciated that the modular nature of the disc prosthesis 20 offers several advantages. For example, if either of the articular components 22a, 22b or the articular ball 24 begins to malfunction or exhibits signs of wear, the disc prosthesis 20 can be easily disassembled by simply removing the set screws 30, 32 and sliding the articular inserts 28 and the articular ball 24 out from the endplates 26. Notably,
10 removal of the articular inserts 28 and the articular ball 24 can be done *in situ* without having to remove the endplates 26 from the intervertebral disc space. This is particularly advantageous if bone on-growth onto the endplates 26 has already commenced, thereby avoiding having to break the bony engagement between the endplates 26 and adjacent vertebral bone.

15 The modular nature of the disc prosthesis 20 also allows the articulating characteristics and movements to be revised without having to remove the entire disc prosthesis 20 from the intervertebral disc space. Notably, the articular components 22a, 22b and the articular ball 24 originally implanted within the intervertebral disc space can be removed from the endplates 26 and replaced with different types/configurations
20 of articular inserts 28 and/or a different articular ball 24 designed to provide the disc prosthesis 20 with modified articulating characteristics and movements. Once again, removal of the articular inserts 28 and the articular ball 24 can be done *in situ* without removing the endplates 26 from the intervertebral disc space. Additionally, the articular components 22a, 22b and the articular ball 24 may be removed from the
25 endplates 26 and replaced with a rigid spacer element to provide rigid stabilization between the adjacent vertebrae, or by a semi-rigid or flexible spacer element to provide flexible stabilization between the adjacent vertebrae.

Referring to FIG. 13, shown therein is a lateral view of a portion of the spinal column, illustrating a pair of adjacent upper and lower vertebrae V_U , V_L separated by a
30 natural intervertebral disc D. As discussed above, in cases where the natural intervertebral disc D is diseased or degenerated, most if not all of the natural disc D is

typically removed via a discectomy or a similar surgical procedure, the details of which would be known to one of ordinary skill in the art.

As illustrated in FIGS. 14 and 15, removal of the diseased or degenerated disc D results in the formation of an intervertebral disc space S between the upper and lower vertebrae V_U , V_L . To accommodate for the insertion of the disc prosthesis 20 within the intervertebral disc space S, preparation of the upper and lower vertebrae V_U , V_L is required. In one embodiment of the invention, the intervertebral space S is enlarged by forming elongate openings or recesses 300 along the inferior and superior portions of the upper and lower vertebrae V_U , V_L , respectively. The elongate recesses 300 preferably have a shape and configuration that substantially corresponds to the outer profile of the central axial portions 50 of the articular components 22a, 22b. In one embodiment, the elongate recesses 300 have a hemi-cylindrical shape; however, other shapes and configurations of the recesses 300 are also contemplated as would occur to one of skill in the art, including other types of arcuate configurations, a rectangular configuration, or other types of polygonal configurations.

In one embodiment of the invention, the elongate recesses 300 extend from an anterior side 302 of the vertebrae V_U , V_L toward a posterior side 304 of the vertebrae V_U , V_L to a predetermined depth d . In a preferred embodiment of the invention, the predetermined depth d of the elongate recesses 300 is approximately equal to or slightly greater than the length l of the central axial portions 50 of the articular components 22a, 22b. As will be discussed in further detail below, forming the recesses 300 at a predetermined depth d correspondingly controls the insertion depth of the disc prosthesis 20 to ensure proper positioning of the disc prosthesis 20 within the intervertebral disc space S. In one embodiment of the invention, the elongate recesses 300 are formed by reaming. However, other methods of forming the recesses 300 are also contemplated as would occur to one of ordinary skill in the art, such as, for example, by drilling, chiseling or curetting.

Referring to FIGS. 16 and 17, following preparation of the upper and lower vertebrae V_U , V_L , the disc prosthesis 20 may then be implanted within the intervertebral disc space S. In one embodiment of the invention, implantation is accomplished by inserting the cylindrical axial portions 50 of the articular components 22a, 22b within the elongate recesses 300, with the bearing surfaces of the lateral flanges 54, 56 and the

axial lip 58 facing the vertebral endplates of the upper and lower vertebrae V_U , V_L . The end surface 94 of the axial lip 58 faces a posterior direction, with the recessed area 96 defined by the axial lip 58 (FIG. 5) providing sufficient clearance to avoid encroachment into the area adjacent the spinal canal.

5 Prior to implantation of the disc prosthesis 20 within the intervertebral disc space S, the articular components 22a, 22b are preferably placed in a predetermined relationship with respect to one another. In one embodiment of the invention, an insertion instrument (not shown) may be used to position and secure the articular components 22a, 22b at a predetermined spacing and at a predetermined orientation
10 relative to one another. The insertion instrument would maintain the articular components 22a, 22b at the predetermined spacing and orientation during manipulation of the disc prosthesis 20, and would be capable of selectively releasing the disc prosthesis 20 once properly positioned within the intervertebral disc space S. Such insertion instrument may include, for example, a pair of prongs adapted for insertion
15 within the axial openings 124 formed in the articular inserts 28 of the articular components 22a, 22b.

As should be appreciated, the specific angular relationship between the articular component 22a, 22b is dictated by the geometry of the upper and lower vertebrae V_U , V_L and the particular curvature or lordosis of the portion of the spinal column being
20 treated. As such, the relative angular orientation of the planes P_1 and P_2 defined along the bearing surfaces 70 of the endplate flanges 54, 56 should correspond to the particular geometric configuration of the natural intervertebral disc D. As should also be appreciated, the distance between the planes P_1 and P_2 should be approximately equal to the height of the natural intervertebral disc D. Additionally, although the
25 bearing surfaces 70 of the endplate flanges 54, 56 have been illustrated and described as having a substantially planar configuration, it should be understood that the bearing surfaces 70 may take on other configurations. For example, the bearing surfaces 70 may take on a curved or arcuate configuration that corresponds to the particular contour of the adjacent vertebral endplate against which the bearing surfaces 70 are engaged.

30 In one embodiment of the invention, the disc prosthesis 20 is inserted between the upper and lower vertebrae V_U , V_L in a direction generally parallel to its longitudinal axis L, with the central axial portions 50 of the endplates 26 being axially displaced

through the elongate recesses 300. Notably, since the central axial portions 50 are axially displaced through the preformed recesses 300, distraction of the upper and lower vertebrae V_U , V_L to accommodate insertion of the disc prosthesis 20 is minimized, if not eliminated entirely. In the illustrated embodiment of the invention, the disc prosthesis 20 is inserted into the intervertebral disc space S via an anterior approach. However, it should be understood that the elongate recesses 300 may alternatively extend from the posterior side 304 of the vertebrae V_U , V_L toward the anterior side 302 at a predetermined depth d to accommodate insertion of the disc prosthesis 20 into the intervertebral disc space S via a posterior approach. It should also be understood that the elongate recesses 300 may alternatively extend from a first lateral side of the vertebrae V_U , V_L toward an opposite lateral side of the vertebrae at a predetermined depth d to accommodate insertion of the disc prosthesis 20 into the intervertebral disc space S via a lateral approach.

As discussed above, the depth d of the elongate recesses 300 is approximately equal to or slightly greater than the length l of the central axial portions 50 of the endplates 26. Accordingly, precise position of the disc prosthesis 20 within the intervertebral disc space S is possible. Specifically, proper axial positioning of the disc prosthesis 20 is accomplished when the insertion ends 64 of the central axial portions 50 bottom out against the axially facing end surfaces 301 of the elongate recesses 300. Controlling the insertion depth of the disc prosthesis 20 results in more precise positioning to avoid over-insertion or under-insertion of the disc prosthesis 20. Additionally, disposition of the central axial portions 50 within the elongate recesses 300 substantially prevents lateral and/or rotational movement of the articular components 22a, 22b with respect to the upper and lower vertebrae V_U , V_L . The relatively large surface area of the central axial portions 50 contacting the upper and lower vertebrae V_U , V_L also tends to minimize subsidence into the cancellous bone. Moreover, engagement of the bearing surfaces of the lateral flanges 54, 56 and the axial lip 58 against the upper and lower vertebrae V_U , V_L tends to minimize subsidence of the disc prosthesis 20 into the cancellous bone.

Once the articular components 22a, 22b are properly positioned within the intervertebral disc space S, the axial lip 58 of the endplates 26 will bear against the posterior cortical rim of the upper and lower vertebrae V_U , V_L . Additionally, the

anterior ends of the central axial portions 50 will bear against the anterior cortical rim of the upper and lower vertebrae V_U , V_L . Moreover, the lateral flanges 54, 56 may be configured to bear against the lateral cortical rim and/or the anterior cortical rim of the upper and lower vertebrae V_U , V_L . Such bearing engagement between the endplates 26
5 of the articular components 22a, 22b and the outer rim of the upper and lower vertebrae V_U , V_L provides additional stabilization of the disc prosthesis 20 and tends to minimize subsidence. Additionally, the teeth 74 formed along the lateral flanges 54, 56 grip the bony endplates of the upper and lower vertebrae V_U , V_L to resist migration of the disc prosthesis 20 and/or to prevent expulsion of the disc prosthesis 20 from the
10 intervertebral disc space S.

The disc prosthesis 20 is initially maintained in position within the intervertebral disc space S relative to the upper and lower vertebrae V_U , V_L via disposition of the central axial portions 50 within the elongate recesses 300 and by engagement of the teeth 74 against the bony vertebral endplates. However, over time
15 the disc prosthesis 20 will be further secured to the upper and lower vertebrae V_U , V_L via bony on-growth onto the surfaces of the articular components 22a, 22b that are in contact with vertebral bone tissue, particularly those surfaces which are in contact with metabolically active cancellous bone. Such bony on-growth provides further resistance to migration of the disc prosthesis 20 and possible expulsion from the intervertebral
20 disc space S. It should be understood that other means for engaging the disc prosthesis 20 to the upper and lower vertebrae V_U , V_L are also contemplated, such as, for example, bone screws, staples, an adhesive, or by other methods of engagement that would occur to one of ordinary skill in the art.

In use, the articular components 22a, 22b and the articular ball 24 cooperate to
25 provide a ball-and-socket type joint that permits relative pivotal and rotational movement between the articular components 22a, 22b, which correspondingly permits relative pivotal and rotational movement between the upper and lower vertebrae V_U , V_L . More specifically, the spherical surface 25 of the articular ball 24 is slidably engaged against the concave surfaces 122 of the articular inserts 28. The resulting
30 pivotal and rotational movement of the articular components 22a, 22b serves to maintain or restore articular motion to the portion of the spinal column being treated

that is substantially similar to the normal bio-mechanical motion provided by a natural intervertebral disc D.

As shown in FIGS. 16 and 17, the unique geometry of the articular components 22a, 22b allows the use of a relatively large articular ball 24. As discussed above, use of an articular ball 24 having a large diameter increases the area of abutment between the convex surface 25 of the ball 24 and the concave surface 122 of the socket 120. As a result, internal stresses within the disc prosthesis 20 are reduced, thereby resulting in decreased wear and prolonged design life of the disc prosthesis 20. Use of a relatively large diameter articular ball 24 is made possible by the hemi-cylindrical central portions 50 of the endplates 26 which are positioned within the hemi-cylindrical recesses 300 formed along the upper and lower vertebrae V_U , V_L . Notably, this unique geometric design allows the use of an articular ball 24 having a diameter greater than the height of the natural intervertebral disc D. As a result, at least a portion of the abutting articular surfaces 25, 122 of the ball 24 and the articular insert 28 is positioned beyond the intervertebral disc space defined between the planes P_1 and P_2 extending along the bearing surfaces 70 of the endplate flanges 54, 56.

Although the disc prosthesis 20 has been illustrated and described as including a pair of articular components 22a, 22b having a separate articular ball 24 disposed therebetween, in an alternative embodiment of the invention the articular ball 24 may be replaced by a protrusion formed integral with one of the articular inserts 28. In this alternative embodiment, the protrusion extending from one of the articular inserts 28 would be at least partially disposed within the socket 120 defined by the opposing articular insert 28. A convex articular surface defined by the protrusion would cooperate with the concave articular surfaces 122 defined by the opposing socket 120 to provide pivotal and rotational articulating motion between the articular components 22a, 22b.

Additionally, although the devices and methods illustrated and described above are particularly useful in treating the lumbar region of the spine, it should nevertheless be understood that the present invention is also applicable to other portions of the spine, including the cervical or thoracic regions of the spine.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in

character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

WHAT IS CLAIMED IS:

1. An articular disc prosthesis for disposition between a first vertebra and a second vertebra, comprising:

a first articular component including a first bearing surface adapted to engage
5 the first vertebra; and

a second articular component including second bearing surface adapted to engage the second vertebra, said first and second bearing surfaces defining a space therebetween; and

wherein at least one of said first and second articular components includes a
10 concave articular surface that cooperates with a corresponding convex articular surface to provide articulating motion between the first and second articular components, at least a portion of said concave articular surface positioned beyond said space.

2. The articular disc prosthesis of claim 1, wherein each of said first and
15 second articular components includes a concave articular surface that cooperates with said corresponding convex articular surface to provide said articulating motion, at least a portion of each of said concave articular surface positioned beyond said space.

3. The articular disc prosthesis of claim 2, further comprising an articular
20 ball positioned between said first and second articular components, said articular ball cooperating with each of said concave articular surfaces to provide said articulating motion.

4. The articular disc prosthesis of claim 1, wherein said first and second
25 bearing surfaces include means for gripping vertebral bone.

5. An articular disc prosthesis for replacement of a natural intervertebral disc, comprising:

a first articular component defining a first concave articular surface;
30 a second articular component defining a second concave articular surface; and
an articular ball positioned between said first and second concave articular surfaces to provide articulating motion between the first and second articular

components, said articular ball having a diameter greater than a height of the natural intervertebral disc.

6. An articular disc prosthesis for disposition between a first vertebra and a
5 second vertebra, comprising:
a first articular component adapted to engage the first vertebra; and
a second articular component adapted to engage the second vertebra; and
wherein each of said first and second articular components extends along an
axis and includes a central axial portion defining a convex lateral curvature and a pair
10 of flanges extending laterally from said central axial portion in generally opposite
directions.

7. The articular disc prosthesis of claim 6, wherein said central axial
portion has a hemi-cylindrical shape.

15

8. The articular disc prosthesis of claim 6, wherein each of said pair of
flanges includes an outwardly facing bearing surfaces configured to engage a respective
one of the first and second vertebrae.

20 9. The articular disc prosthesis of claim 8, wherein said outwardly facing
bearing surfaces include means for gripping vertebral bone.

10. The articular disc prosthesis of claim 6, wherein said pair of flanges of
said first articular component defines a first pair of inwardly facing surfaces, said pair
25 of flanges of said second articular component defining a second pair of inwardly facing
surfaces arranged generally opposite said first pair of inwardly facing surfaces, at least
one of said first and second pairs of inwardly facing surfaces defining an outward taper.

11. The articular disc prosthesis of claim 10, wherein said outward taper
30 extends in a lateral direction.

12. The articular disc prosthesis of claim 11, wherein said outward taper extends in an axial direction.

13. The articular disc prosthesis of claim 10, wherein each of said first and second pairs of inwardly facing surfaces defines an outward taper.

14. The articular disc prosthesis of claim 6, further comprising a spherical-shaped ball disposed between said first and second articular components to provide articulating motion therebetween, said spherical-shaped ball being at least partially positioned within said central axial portion of said first and second articular components.

15. The articular disc prosthesis of claim 6, wherein each of said first and second articular components includes a lip extending axially from said central axial portion, said lip including an outwardly facing bearing surface configured to engage a respective one of the first and second vertebrae.

16. The articular disc prosthesis of claim 15, wherein said lip includes an axially facing surface, said axially facing surface defining a recessed area extending inwardly toward said central axial portion.

17. An articular disc prosthesis for disposition between a first vertebra and a second vertebra, comprising:

a first modular articular component; and

a second modular articular component; and

wherein each of said first and second modular articular components includes:

an outer shell portion configured to engage a corresponding one of the first and second vertebrae; and

an inner insert portion removably engaged with the outer shell portion, said inner insert portion including an articular surface cooperating with a corresponding articular surface to provide articulating motion between said first and second modular articular components.

18. The articular disc prosthesis of claim 17, further comprising an articular ball positioned between said first and second modular articular components; and wherein said articular surface of each of said inner insert portions is a concave articular surface, said articular ball cooperating with said concave articular surfaces to provide said articulating motion.

19. The articular disc prosthesis of claim 18, wherein said inner insert portions are formed of a first material, said articular ball formed of a second material different from said first material.

20. The articular disc prosthesis of claim 19, wherein one of said first and second materials is a metallic material, and wherein the other of said first and second materials is a plastic material.

21. The articular disc prosthesis of claim 17, wherein said inner insert portion is slidably disposed within said outer shell portion and is securely engaged thereto by a number of fasteners.

22. A method of implanting an articular disc prosthesis between first and second vertebrae, comprising:
providing an articular disc prosthesis having a first articular component adapted to engage a first vertebra and a second articular component adapted to engage a second vertebra, each of the first and second articular components extending along an axis and including a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally from the central axial portion in generally opposite directions;

removing at least a portion of a natural intervertebral disc from between the first and second vertebrae to form an intervertebral space;
forming an elongate recess along a central region of each of the first and second vertebrae; and
implanting the articular disc prosthesis within the intervertebral space by

inserting the central axial portions of the first and second articular components within the elongate recesses of the first and second vertebrae.

23. The method of claim 22, wherein the inserting comprises axially
5 displacing the central axial portions of the first and second articular components along the elongate recesses in the first and second vertebrae.

24. The method of claim 22, further comprising controlling the forming of
the elongate recesses to a predetermined depth.
10

25. The method of claim 24, wherein the central axial portions of the first
and second articular components have an axial length substantially equal to the
predetermined depth of the elongate recesses.

26. The method of claim 25, wherein the forming of the elongate recesses
comprises reaming.
15

27. The method of claim 22, further comprising engaging the pair of flanges
of each of the first and second articular components against the vertebral endplate of a
corresponding one of the first and second vertebrae.
20

28. The method of claim 22, wherein the central axial portion of the first and
second articular components and the elongate recesses formed in the first and second
vertebrae each have a hemi-cylindrical configuration.
25

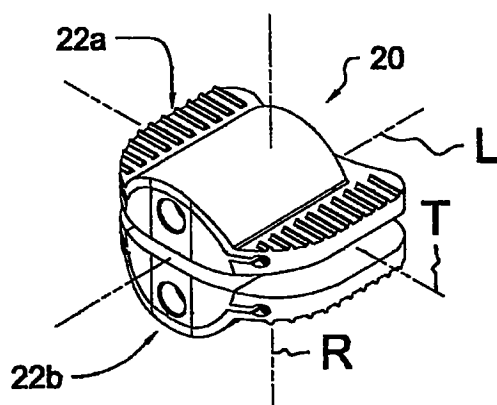


Fig. 1

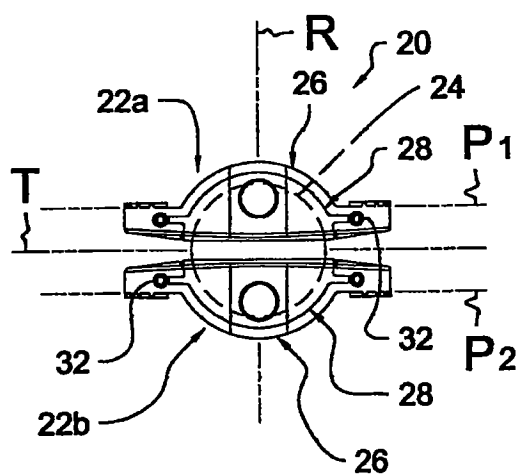


Fig. 2

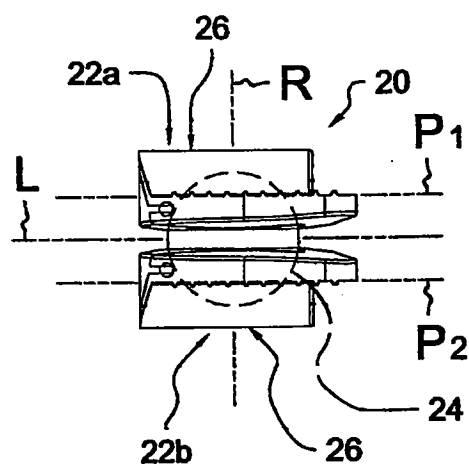


Fig. 3

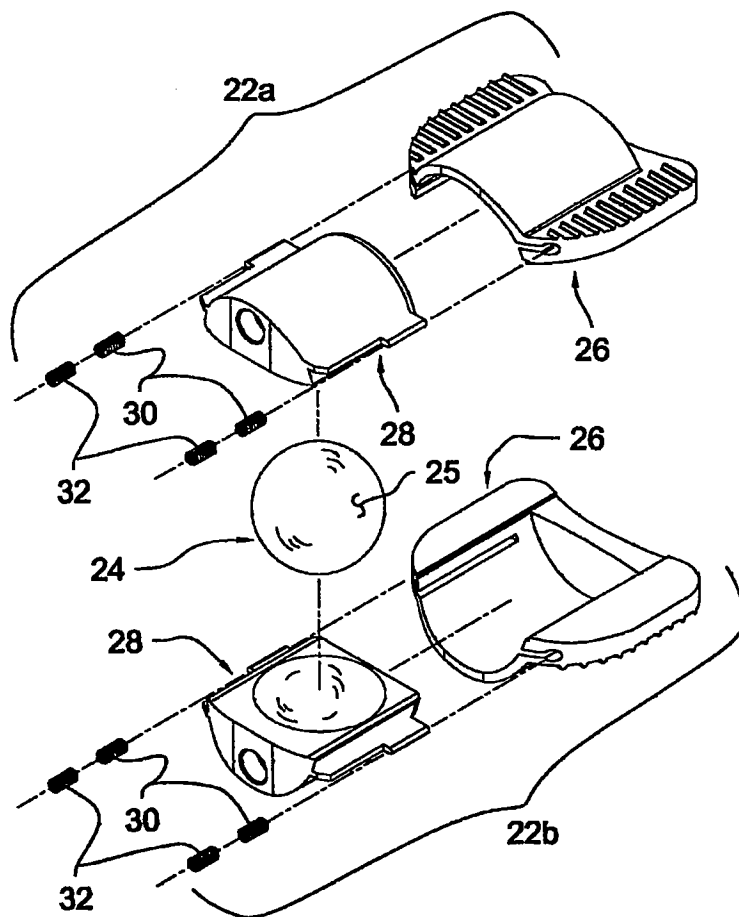
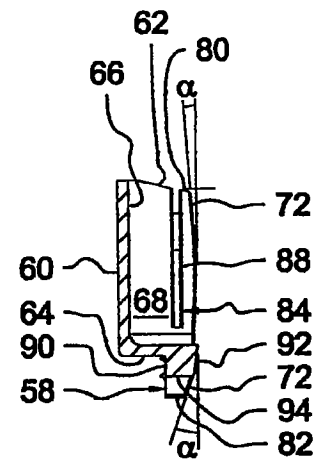
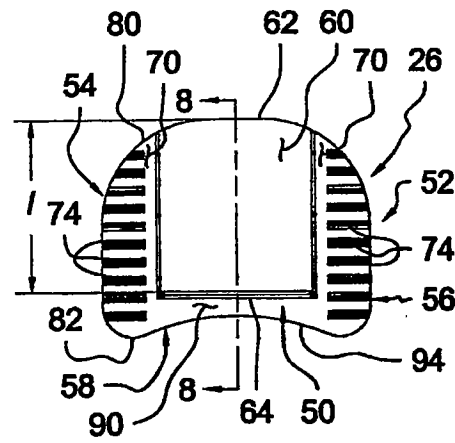
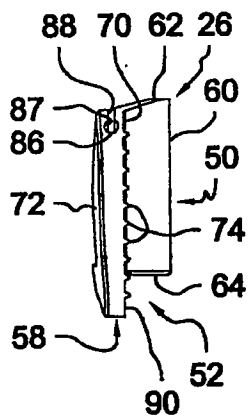
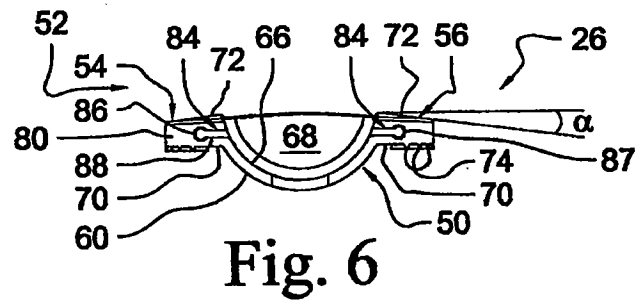


Fig. 4



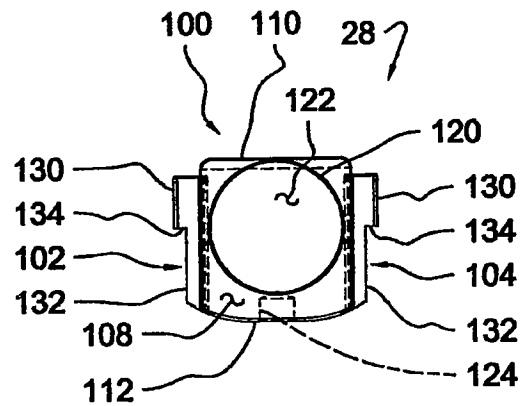


Fig. 10

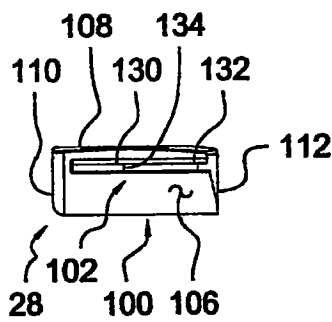


Fig. 11

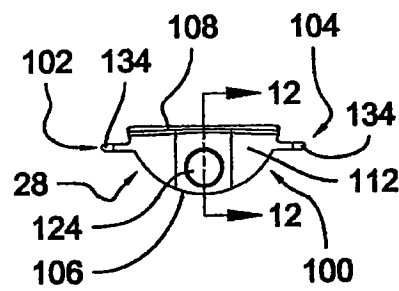


Fig. 9

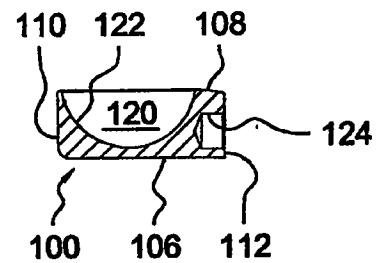


Fig. 12

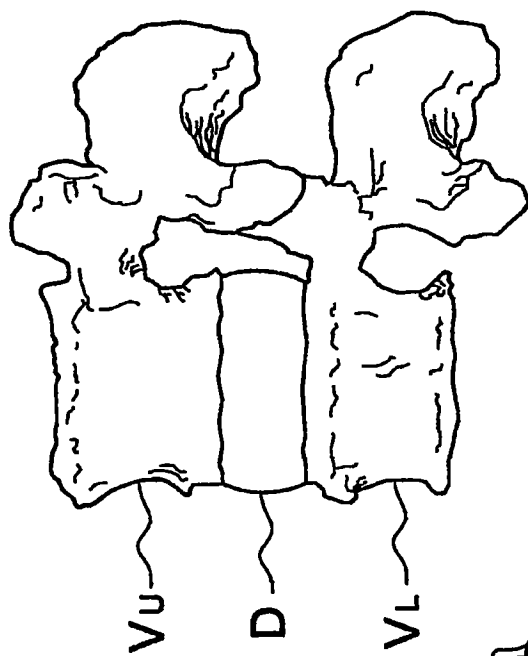


Fig. 13

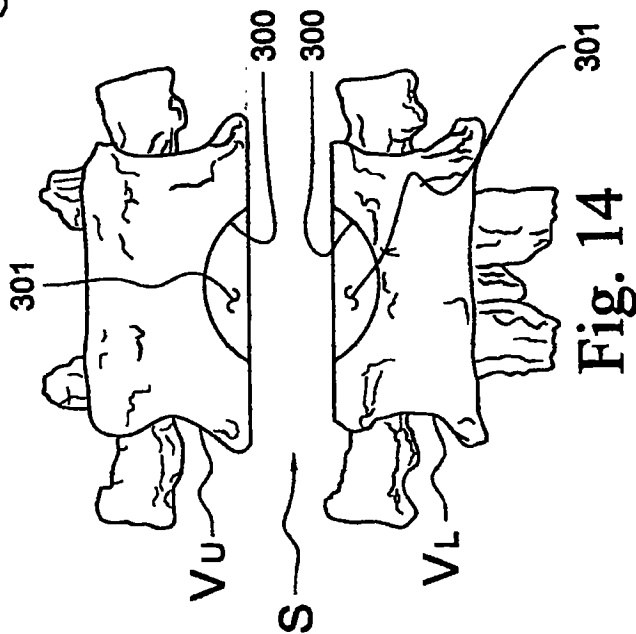


Fig. 14

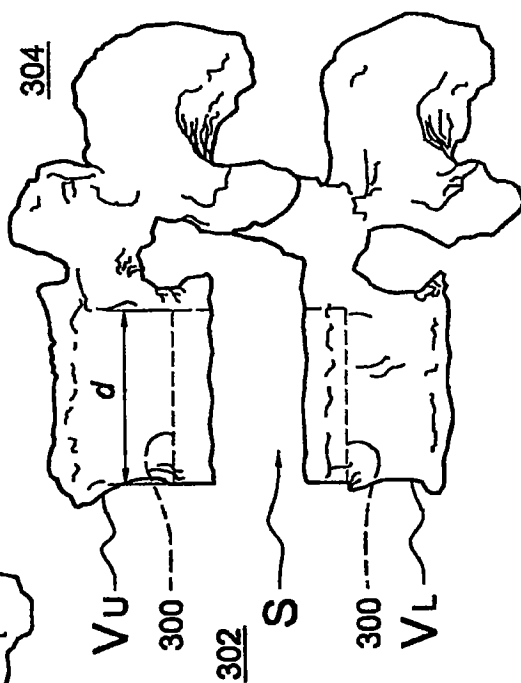


Fig. 15

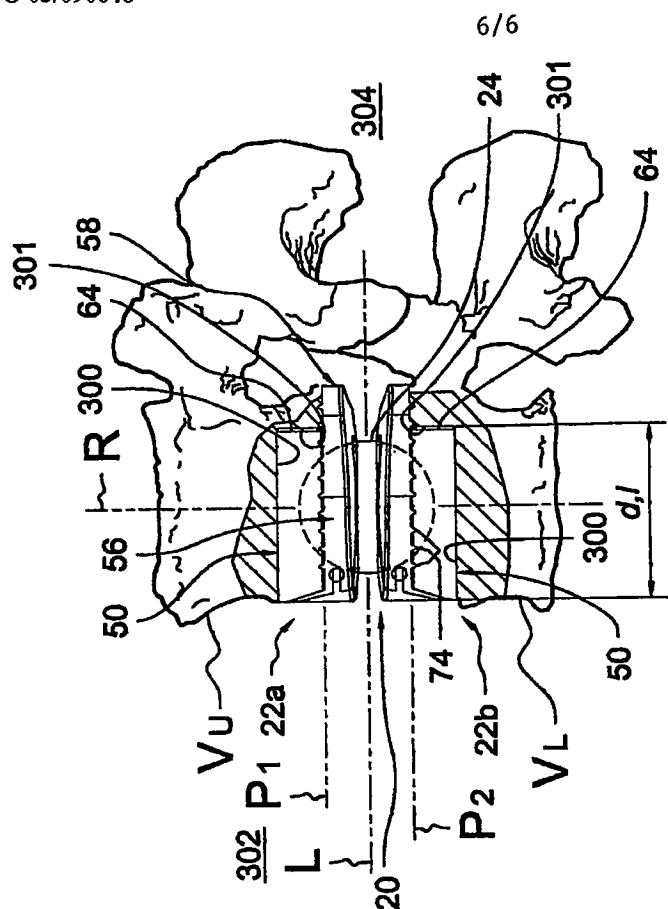


Fig. 17

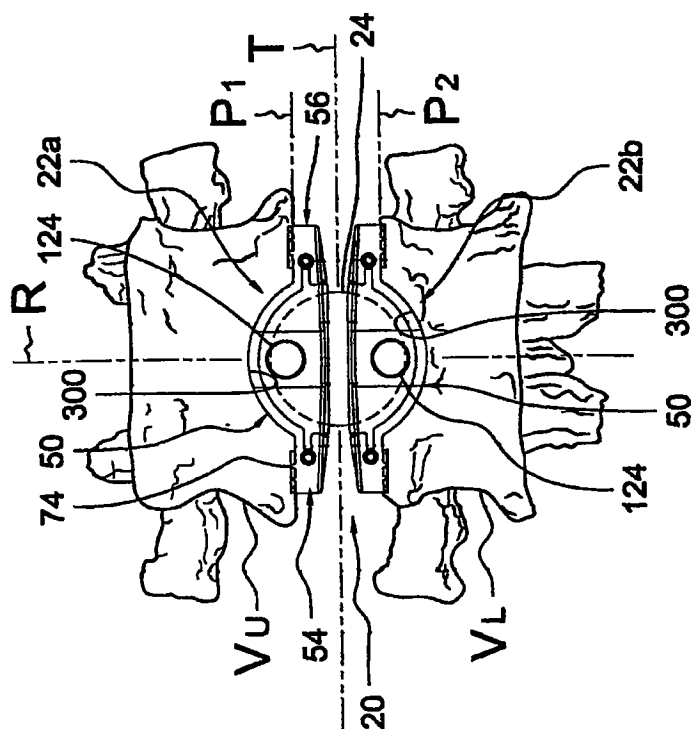


Fig. 16

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 03/12337

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPÜ-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 28 04 936 A (SULZER AG) 2 August 1979 (1979-08-02) page 4, last paragraph -page 5, paragraph 4; figure 1	1-3, 5-8
X	EP 0 955 021 A (LINK WALDEMAR GMBH CO) 10 November 1999 (1999-11-10) claim 1; figure 7	1, 2, 4
X	FR 2 801 782 A (GRAF HENRY) 8 June 2001 (2001-06-08) figure 4	1-3
X	WO 01 64140 A (BUHLER MARKUS ; RAMADAN AYMEN (CH); SCIENT X (FR)) 7 September 2001 (2001-09-07) abstract	17
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12337

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) figure 1	17
A	FR 2 805 985 A (EUROSURGICAL) 14 September 2001 (2001-09-14) claim 1	1

INTERNATIONAL SEARCH REPORT

international application No.
PCT/US 03/12337

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 22-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US 03/12337

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
DE 2804936	A	02-08-1979	CH	624573 A5	14-08-1981
			DE	2804936 A1	02-08-1979
			NL	7900195 A	03-08-1979
EP 0955021	A	10-11-1999	EP	0955021 A1	10-11-1999
			AT	205691 T	15-10-2001
			DE	59801514 D1	25-10-2001
			ES	2163216 T3	16-01-2002
			HK	1023496 A1	18-01-2002
FR 2801782	A	08-06-2001	FR	2801782 A1	08-06-2001
			AU	2182401 A	12-06-2001
			CA	2392868 A1	07-06-2001
			EP	1233711 A1	28-08-2002
			WO	0139678 A1	07-06-2001
			JP	2003515381 T	07-05-2003
			US	2003055427 A1	20-03-2003
WO 0164140	A	07-09-2001	FR	2805733 A1	07-09-2001
			AU	3933701 A	12-09-2001
			EP	1263352 A1	11-12-2002
			WO	0164140 A1	07-09-2001
			US	6517580 B1	11-02-2003
WO 0101893	A	11-01-2001	DE	29911422 U1	12-08-1999
			WO	0101893 A1	11-01-2001
			AU	7224500 A	22-01-2001
			BR	9917397 A	05-03-2002
			CA	2391330 A1	11-01-2001
			EP	1194088 A1	10-04-2002
			JP	2003503154 T	28-01-2003
FR 2805985	A	14-09-2001	FR	2805985 A1	14-09-2001
			EP	1261302 A1	04-12-2002
			WO	0168003 A1	20-09-2001

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Ab-
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(72) Erfinder; und

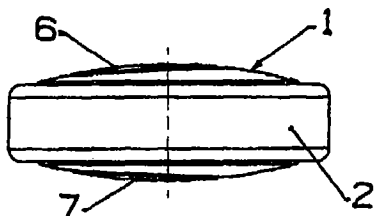
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(54) Title: INTERVERTEBRAL PROSTHESIS OR NUCLEUS REPLACEMENT PROSTHESIS

WO 03/084444 A1

(54) Bezeichnung: BANDSCHEIBENPROTHESE ODER NUKLEUS-ERSATZ-PROTHESE



(57) Abstract: Disclosed is an intervertebral prosthesis or nucleus replacement prosthesis (1) comprising a longitudinal, elastic, coilable body (2), a first, outer end (3), a second, inner end (4), and a longitudinal central axis (5). The cross section (10) of the body (2), which is perpendicular relative to the central axis (5), decreases towards the second, inner end (4).

(57) Zusammenfassung: Die Bandscheibenprothese oder Nukleus-Ersatz-Prothese (1), besteht aus einem longitudinalen, formelastischen, spiralförmig aufwickelbaren Körper (2), mit einem ersten, äusseren Ende (3), einem zweiten, inneren Ende (4) und einer longitudinalen Zentralachse (5). Der zur Zentralachse

(5) orthogonale Querschnitt (10) des Körpers (2) verkleinert sich gegen das zweite, innere Ende (4) hin.

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Bandscheibenprothese oder Nukleus-Ersatz-Prothese

Die Erfindung betrifft eine Bandscheibenprothese oder Nukleus-Ersatz-Prothese gemäss dem Oberbegriff des Patentanspruchs 1.

Solche Prothesen werden nach Entfernung der beschädigten, natürlichen Bandscheibe oder des beschädigten Nukleus einer Bandscheibe in den Zwischenwirbelraum zweier benachbarter Wirbelkörper eingebracht. Dabei besteht das Ziel, wieder möglichst natürliche Zustände herbeizuführen, d.h. insbesondere wieder die ursprüngliche Bandscheibenhöhe und damit den ursprünglichen Abstand zwischen den beiden benachbarten Wirbelkörpern wiederherzustellen.

Aus dem Stand der Technik sind bereits Bandscheibenprothesen bekannt, so z.B. aus der FR-A-2 712 486 BRESLAVE, bei welcher ein biegbares, aber nicht formelastisches VELKRO-Band spiralförmig zu einer Kreisscheibe aufgewickelt ist. Um die spiralförmige Aufwicklung des Bandes zu ermöglichen benötigt diese bekannte Prothese ein zylindrisches Mittelstück, an welchem das Band befestigt wird und dann durch Rotation des Mittelstücks darauf aufgewickelt wird.

Nachteilig bei dieser bekannten Bandscheibenprothese ist der Übergang zwischen dem relativ grossen Mittelstück und dem relativ schmalen Band sowie die fehlende Formelastizität des Bandes. Die Grösse des Mittelstücks bestimmt auch gleichzeitig die Grösse der Eintrittsöffnung, wobei letztere so klein als möglich gehalten werden sollte, was aber bei dieser bekannten Prothese nicht möglich ist.

Aus der EP-A-0 773 008 ist eine Zwischenwirbelprothese gemäss dem Oberbegriff des Anspruchs 1 bekannt. Nachteilig bei dieser bekannten Prothese ist wiederum das relativ grosse zylinderförmige Mittelstück an welchem der längliche, spiralförmige Körper über ein als Gelenk wirkendes Übergangsglied geringerer Breite befestigt ist. Das zylinderförmige Mittelstück mit dem nachfolgenden gelenkigen Übergangsglied ist, weil es eben federnd gelenkig angeformt ist, schwierig und aufwendig zu handhaben. Das zylinderförmige Mittelstück ist zudem hinderlich.

Die obenstehende Diskussion des Standes der Technik erfolgt lediglich zur Erläuterung des Umfeldes der Erfindung und bedeutet nicht, dass der zitierte Stand der Technik zum Zeitpunkt dieser Anmeldung oder ihrer Priorität auch tatsächlich publiziert oder öffentlich bekannt war.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt das Problem zugrunde, eine Bandscheibenprothese oder Nukleus-Ersatz-Prothese zu schaffen, welche dank ihrer

geometrischen Form die Bandscheibenhöhe restauriert, auftretende Belastungskräfte auf der ganzen - vorteilhafterweise konvex gestalteten - Oberfläche aufnimmt und den Druck in den Facettengelenken entlastet, Kräfte in den Anulus ableitet und die natürliche Bewegung nicht beeinträchtigt, sondern abstützt.

Durch das verkleinerte innere Ende der Bandscheibenprothese oder Nukleus-Ersatz-Prothese wird eine vereinfachte Handhabung des Instrumentariums ermöglicht. Der Widerstand beim Einziehen des Implantates in das Einführungsinstrument wird dadurch geringer.

Da die Endplattenmitte sehr dünn ist, kann sie relativ einfach eingedrückt werden; dank des dünneren Querschnitts im Zentrum des Implantates ist dieses als relativ flexible Zone ausgebildet, so dass die auftretenden Drücke besser absorbiert werden.

Die Erfindung löst die gestellte Aufgabe mit einer Bandscheibenprothese, welche die Merkmale des Anspruchs 1 aufweist.

Die Verkleinerung des zur Zentralachse orthogonalen Querschnitts erfolgt vorzugsweise kontinuierlich und bevorzugt gegen das erste, äussere Ende des Körpers hin. Die senkrecht zur Zentralachse gemessene Breite des Körpers sollte sich - von seiner Mitte aus gesehen - ebenfalls gegen das äussere Ende hin - vorzugsweise kontinuierlich - verringern. Zusätzlich kann sich die Breite auch gegen das innere Ende hin, vorzugsweise

kontinuierlich verringern. Dadurch wird eine erhöhte Flexibilität für das Instrumentarium zur Handhabung des Implantates erreicht.

Die Breite des Körpers ist in seiner Mitte typischerweise 50 % bis 500 %, vorzugsweise 100 % bis 300 % breiter als an seinem inneren und äusseren Ende. Dadurch kann die individuelle Flexibilität angesteuert werden und man erhält eine grössere Auflagefläche zu den Deckplatten der Wirbelkörper.

Bei einer speziellen Ausführungsform weist der Körper im spiralförmig aufgewickelten Zustand zur Zentralachse eine obere Spiralfäche und eine untere Spiralfäche auf, welche beide konvex gewölbt und zur Anlage an die Deckplatten zweier benachbarter Wirbelkörper geeignet sind. Damit wird eine Selbstzentrierung des Implantates in den konkaven Endplatten der Wirbelkörper und Erhöhung der Auflagefläche sowie eine Verringerung der spezifischen Flächenpressung erzielt. Insgesamt ergibt sich eine bessere Kräfteeinleitung in den Anulus und die Endplatte.

Zweckmässigerweise weist der Körper im spiralförmig aufgewickelten, nicht belasteten Zustand zwischen den Spiralen einen Spalt auf, was einerseits die Produktion des Körpers erleichtert und anderseits eine optimale Flexibilität garantiert. Der Spalt sollte eine Breite von mindestens 0,4 mm, vorzugsweise mindestens 0,5 mm aufweisen. Anderseits sollte der

Spalt höchstens 1,0 mm, vorzugsweise höchstens 0,8 mm breit sein. Innerhalb dieser Grenzen ergibt sich ein optimaler Memory-Effekt des spiralförmig aufgewickelten Körpers.

Bei einer speziellen Ausführungsform weist der Körper im spiralförmig aufgewickelten Zustand, in der Spiralebene gesehen eine ovale oder nierenförmige Gestalt auf, vorzugsweise mit einer in der Spiralebene gemessenen Fläche von 250 bis 750 mm², was eine optimale Anpassung an die anatomischen Randbedingungen ergibt.

Bei einer bevorzugten Ausführungsform enthält der Körper ein Hydrogel oder besteht sogar ausschliesslich aus einem Hydrogel. Hydrogele sind Kolloide, bei denen die disperse Phase (Kolloid) sich mit der kontinuierlichen Phase (Wasser) zu einem viskosen, gelartigen Produkt verbunden hat, z.B. koagulierte Siliziumsäure. Gegenüber anderen Materialien ergibt sich der Vorteil der Wasser-Abgabe unter Druck und der Wasser-Aufnahme bei Druckentlastung, d.h. analog zum natürlichen Nukleus.

Zweckmässigerweise wird der Körper spritzgusstechnisch hergestellt, wobei sein Anspritzpunkt vorzugsweise im Bereich des zweiten Endes positioniert ist. Dies bedeutet ist in der Produktion fülltechnisch von Vorteil. Der Anspritzpunkt ist vorzugsweise versenkt angeordnet. Die Verwerfungen, die durch das Abziehen der Nadeldüse entstehen, kommen dadurch nicht an der Oberfläche vor, sondern in der Ansenkung drin.

Bei einer speziellen Ausführungsform ist das erste Ende asymmetrisch zum Inneren der Spirale zulaufend ausgebildet. Dadurch ist die Aussenform des spiralförmig aufgewickelten Körpers abgerundet.

Der Körper kann röntgenopak ausgebildet werden, vorzugsweise durch einen Zusatz von Bariumsulfat. Damit wird eine Überprüfung der Lage des Implantates und die Kontrolle einer allfälligen Migration ermöglicht. Der Körper kann zum gleichen Zweck auch röntgenopake Elemente, vorzugsweise in Form von Filamenten, Drähten oder Kügelchen enthalten.

Bei einer speziellen Ausführungsform weist die letzte, äussere Spiralwindung von mindestens 360° Umfang des spiralförmig aufgewickelten Körpers - gegenüber den übrigen Spiralwindungen - einen dünneren Querschnitt auf. Der äussere Rand des Implantats ist dadurch flexibler bezogen auf die Funktion des Implantates.

Schliesslich kann das äussere Ende des Körpers mit Mitteln versehen sein, welche für die Erfassung der Bandscheibenprothese mittels eines Einführungsinstrumentes geeignet sind, vorzugsweise in Form von Vertiefungen oder Erhebungen.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der schematischen Darstellungen eines Ausführungsbeispiels noch näher erläutert.

Es zeigt

Fig. 1 eine perspektivische Ansicht einer erfindungsgemässen Bandscheibenprothese;

Fig. 2 zeigt einen horizontalen Querschnitt durch die Bandscheibenprothese nach Fig. 1;

Fig. 3 einen Querschnitt längs der Linie III-III in Fig. 2;

Fig. 4 eine Seitenansicht der Bandscheibenprothese nach Fig. 1;

Fig. 5 einen vergrösserten Ausschnitt in der Fig. 3 im Bereich des zentralen Anspritzpunktes;

Fig. 6 eine vergrösserte, perspektivische Ansicht des äusseren Endes des spiralförmig aufgewickelten Körpers gemäss Fig. 1; und

Fig. 7 eine Variante des äusseren Endes des spiralförmig aufgewickelten Körpers gemäss Fig. 1.

Die in den Fig. 1 bis 4 dargestellte Bandscheibenprothese 1 besteht aus einem longitudinalen, formelastischen, spiralförmig aufwickelbaren Körper 2 mit einem ersten, äusseren Ende 3,

einem zweiten, inneren Ende 4 und einer longitudinalen Zentralachse 5. Der zur Zentralachse 5 orthogonale Querschnitt 10 des Körpers 2 verkleinert sich kontinuierlich - wie in den Fig. 2 und 3 dargestellt - sowohl gegen das zweite, innere Ende 4 hin als auch gegen das erste, äussere Ende 3 hin.

Die in der Fig. 2 gemessene Breite des Körpers 2 beträgt beim inneren Ende 4 etwa 2,5 mm, beim äusseren Ende 3 ebenfalls etwa 2,5 mm und wächst dazwischen gegen die Mitte des Körpers 2 bis auf etwa 4,5 mm an.

Die in der Fig. 3 gemessene Höhe der Bandscheibenprothese 1 entspricht dem anatomischen Zwischenwirbelraum. Die Höhe in der Mitte der konvexen Bandscheibenprothese 1 steht beidseitig um etwas 0,5 bis 3,0 mm vor im Vergleich zu den randständigen Partien.

Im spiralförmig aufgewickelten, nicht belasteten Zustand des Körpers 2 - wie er in Fig. 1 und 2 dargestellt ist - besteht zwischen den einzelnen Spiralwindungen ein Spalt von 0,65 mm.

Der Körper 2 besteht im wesentlichen aus einer Hülle aus Polycarbonaturethan und/oder aus Silikon-Polycarbonaturethan sowie einer Füllung aus einem Polyvinylalkohol-Hydrogel. Weitere geeignete Materialien, sowohl für die Hülle als auch für ihre Füllung, können der noch hängigen Internationalen Patentanmeldung PCT/CH01/00700 entnommen werden.

In Fig. 5 ist dargestellt, wie der Anspritzpunkt 9 im Bereich des zweiten Endes 4, d.h. annähernd im Zentrum des spiralförmigen Körpers 2, positioniert ist und gegenüber der oberen Spiralfäche 6 versenkt angeordnet ist.

Die Fig. 6 zeigt eine mögliche Variante des äusseren Endes 3 des Körpers 2 mit Mitteln, in Form zweier quer zur Zentralachse 5 stehenden Nuten 11, welche eine einfache Erfassung der Bandscheibenprothese mittels eines geeigneten Einführungs-instrumentes, beispielsweise einer Zange gestattet.

Fig. 7 zeigt eine zweite Variante des äusseren Endes 3 des Körpers 2 mit Mitteln, hier in Form zweier quer zur Zentralachse 5 verlaufenden flachen Vertiefungen 12 sowie einem parallel zur Zentralachse 5 angeordneten Schlitz 13 mit einer zylindrischen Hinterschneidung 14.

Patentansprüche

1. Bandscheibenprothese oder Nukleus-Ersatz-Prothese (1), bestehend aus einem longitudinalen, formelastischen, spiralförmig aufwickelbaren Körper (2), mit einem ersten, äusseren Ende (3), einem zweiten, inneren Ende (4) und einer longitudinalen Zentralachse (5),

dadurch gekennzeichnet, dass

der zur Zentralachse (5) orthogonale Querschnitt (10) des Körpers (2) sich gegen das zweite, innere Ende (4) hin verkleinert.

2. Bandscheibenprothese (1) nach Anspruch 1, dadurch gekennzeichnet, dass der orthogonale Querschnitt (10) sich kontinuierlich verkleinert.

3. Bandscheibenprothese (1) nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der zur Zentralachse (5) orthogonale Querschnitt (10) des Körpers (2) sich gegen das erste, äussere Ende (3) hin, vorzugsweise kontinuierlich verkleinert.

4. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass sich die senkrecht zur Zentralachse (5) gemessene Breite des Körpers (2) - von seiner Mitte aus gesehen - gegen das äussere Ende (3) hin, vorzugsweise kontinuierlich verringert.

5. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass sich die senkrecht zur Zentralachse (5) gemessene Breite des Körpers (2) - von seiner Mitte aus gesehen - gegen das innere Ende (4) hin, vorzugsweise kontinuierlich verringert.

6. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Breite des Körpers (2) in seiner Mitte 50 % bis 500 %, vorzugsweise 100 % bis 300 % breiter ist als an seinem inneren und äusseren Ende (4,3).

7. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass der Körper (2) im spiralförmig aufgewickelten Zustand zur Zentralachse (5) eine obere Spiralfäche (6) und eine untere Spiralfäche (7) aufweist, welche beide konvex gewölbt und zur Anlage an die Deckplatten zweier benachbarter Wirbelkörper geeignet sind.

8. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass der Körper (2) im spiralförmig aufgewickelten, nicht belasteten Zustand zwischen den Spiralen einen Spalt aufweist.

9. Bandscheibenprothese (1) nach Anspruch 8, dadurch gekennzeichnet, dass der Spalt eine Breite von mindestens 0,4 mm, vorzugsweise mindestens 0,5 mm aufweist.

10. Bandscheibenprothese (1) nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass der Spalt eine Breite von höchstens 1,0 mm, vorzugsweise von höchstens 0,8 mm aufweist.
11. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass der Körper (2) im spiralförmig aufgewickelten Zustand, in der Spiralebene gesehen eine ovale oder nierenförmige Gestalt aufweist, vorzugsweise mit einer in der Spiralebene gemessenen Fläche von 250 bis 750 mm².
12. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass der Körper (2) ein Hydrogel enthält und vorzugsweise vollständig aus einem Hydrogel besteht.
13. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass der Körper (2) spritzgusstechnisch hergestellt ist und sein Anspritzpunkt (9) im Bereich des zweiten Endes (4) positioniert ist.
14. Bandscheibenprothese (1) nach Anspruch 13, dadurch gekennzeichnet, dass der Anspritzpunkt (9) gegenüber der oberen Spiralfäche (6) versenkt angeordnet ist.
15. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass das erste Ende (3) asymmetrisch zum Inneren der Spirale zulaufend ausgebildet ist.

16. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass der Körper (2) röntgenopak ist, vorzugsweise erzeugt durch einen Zusatz von Bariumsulfat.

17. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass der Körper (2) röntgenopake Elemente, vorzugsweise in Form von Filamenten, Drähten oder Kügelchen enthält.

18. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, dass die letzte, äussere Spiralwindung von mindestens 360° Umfang des spiralförmig aufgewickelten Körpers (2) gegenüber den übrigen Spiralwindungen einen dünneren Querschnitt aufweist.

19. Bandscheibenprothese (1) nach einem der Ansprüche 1 bis 18, dadurch gekennzeichnet, dass das äusseren Ende (3) des Körpers (2) mit Mitteln (11;12,13,14) versehen ist, welche für die Erfassung der Bandscheibenprothese (1) mittels eines Einführungsinstrumentes geeignet sind, vorzugsweise in Form von Vertiefungen oder Erhebungen.

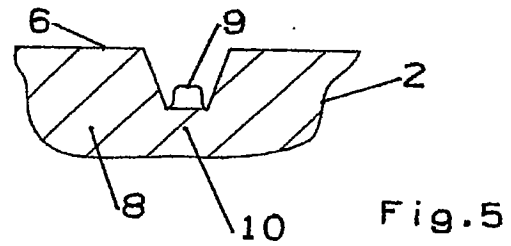
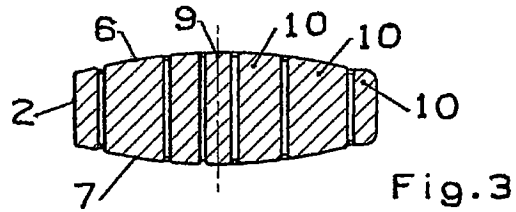
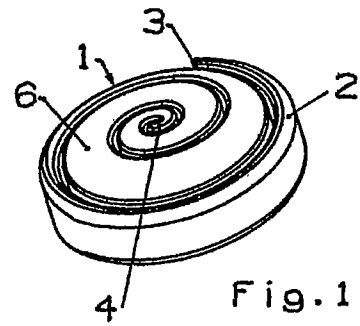
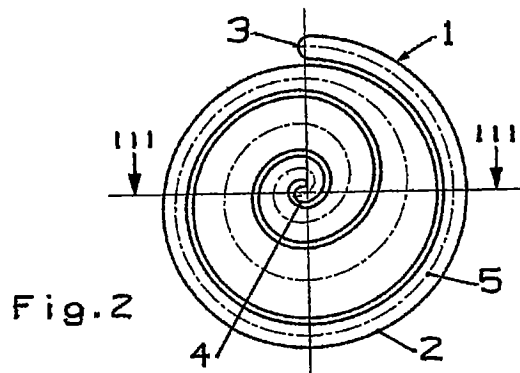
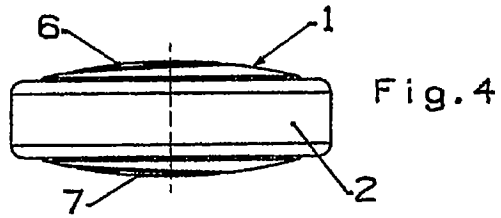


Fig.7

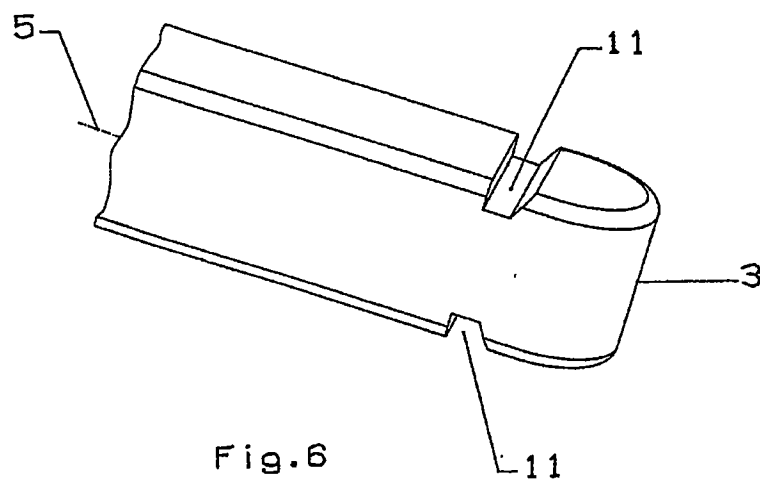
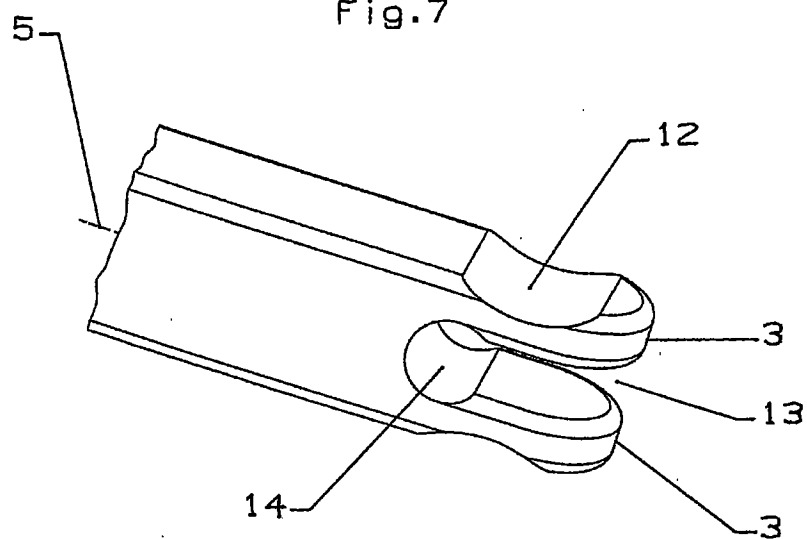


Fig.6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 02/00189

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 157 676 A (SULZER ORTHOPAEDIE AG) 28 November 2001 (2001-11-28) claims 1,13; figures page 3, line 35 ----	1-8,11, 12,15-19
A	EP 0 773 008 A (SULZER ORTHOPAEDIE AG) 14 May 1997 (1997-05-14) cited in the application claims 1,4,6,11,12; figures 1,2 column 6, line 33 - line 39 ----	1-4,6-8, 11,13, 15-19
A	FR 2 712 486 A (CATON PHILIPPE;SIMON GERARD; BRESLAVE PATRICE) 24 May 1995 (1995-05-24) cited in the application claims 1-3,8; figures ----- -/--	1,8,15



Further documents are listed in the continuation of box C.



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Date of the actual completion of the international search

2 December 2002

Date of mailing of the international search report

09/12/2002

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 02/00189

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 02 17824 A (SDGI HOLDINGS INC ;TRIEU HAI H (US)) 7 March 2002 (2002-03-07) figures 12,13 page 15, line 12 - line 27 -----</p>	1,12,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH 02/00189

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1157676	A	28-11-2001	EP 1157676 A1	28-11-2001
			JP 2002028171 A	29-01-2002
EP 0773008	A	14-05-1997	US 5919235 A	06-07-1999
			EP 0773008 A1	14-05-1997
			JP 9164156 A	24-06-1997
			US 6165218 A	26-12-2000
FR 2712486	A	24-05-1995	FR 2712486 A1	24-05-1995
WO 0217824	A	07-03-2002	AU 8535101 A	13-03-2002
			WO 0217824 A2	07-03-2002
			US 2002026244 A1	28-02-2002

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/CH 02/00189

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 7 A61F2/44

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Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 7 A61F

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Während der Internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 1 157 676 A (SULZER ORTHOPAEDIE AG) 28. November 2001 (2001-11-28) Ansprüche 1,13; Abbildungen Seite 3, Zeile 35 ----	1-8,11, 12,15-19
A	EP 0 773 008 A (SULZER ORTHOPAEDIE AG) 14. Mai 1997 (1997-05-14) in der Anmeldung erwähnt Ansprüche 1,4,6,11,12; Abbildungen 1,2 Spalte 6, Zeile 33 - Zeile 39 ----	1-4,6-8, 11,13, 15-19
A	FR 2 712 486 A (CATON PHILIPPE;SIMON GERARD; BRESLAVE PATRICE) 24. Mai 1995 (1995-05-24) in der Anmeldung erwähnt Ansprüche 1-3,8; Abbildungen ----- -/--	1,8,15



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



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Bevollmächtigter Bediensteter

Stach, R

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/CH 02/00189

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie ^a	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 02 17824 A (SDGI HOLDINGS INC ;TRIEU HAI H (US)) 7. März 2002 (2002-03-07) Abbildungen 12,13 Seite 15, Zeile 12 - Zeile 27 -----	1,12,15

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

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EP 1157676	A	28-11-2001	EP	1157676 A1	28-11-2001
			JP	2002028171 A	29-01-2002
EP 0773008	A	14-05-1997	US	5919235 A	06-07-1999
			EP	0773008 A1	14-05-1997
			JP	9164156 A	24-06-1997
			US	6165218 A	26-12-2000
FR 2712486	A	24-05-1995	FR	2712486 A1	24-05-1995
WO 0217824	A	07-03-2002	AU	8535101 A	13-03-2002
			WO	0217824 A2	07-03-2002
			US	2002026244 A1	28-02-2002